PREDICTING ADHERENCE

IN A MULTIFACETED MEDICAL REGIMEN

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Acknowledgments

“…in all your ways acknowledge him,
and he will make your paths straight.”

Proverbs 3:6

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Abstract

Predicting Adherence in a Multifacted Medical Regimen

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Patient nonadherence to medical regimens is acknowledged as a significant problem in patient care and there has been a substantial amount of research focusing on behavioral explanations. Previous research has utilized the Health Belief Model (HBM) to understand and predict adherence, however, it has yielded "lower than expected" predictability (pg. 182; Rosenstock, Strecher, & Becker, 1988). The originators of the HBM have suggested but not tested, the importance of self-efficacy theory in increasing the predictive strength of the current model. The purpose of this study was to assess the predictive strength of the HBM with the added self-evaluative component of self-efficacy, in determining self-care behaviors in individuals with a diagnosis of diabetes mellitus. Participants included 118 individuals with a diagnosed with diabetes mellitus. Individuals were given self-report instruments measuring self-efficacy, health beliefs, and adherence, as well as demographic data. Adherence for 62 participants was also measured via blood assay levels of hemoglobin (HbA1c). Instruments include a demographic questionnaire, the Activities Questionnaire, the Diabetes Health Belief Questionnaire (DHBQ), and the Summary of Diabetes Self-Care Activities (SDSCA). Five hierarchical regression analyses were conducted to determine the amount of variance predicted by the *new* HBM. No significance was found increasing predictability with the Self-Efficacy measure. Findings are discussed within the context

of measurement errors and power. Recent trends in health behavioral change are reviewed and discussed.

CHAPTER 1: INTRODUCTION

1.1 Adherence

"If true tragedy lies in the failure to achieve that which can be achieved, than non-compliance is a tragic flaw in our efforts to reap the benefits of treatments that work when they are taken" (pg. 156; Haynes, Wang, & Da Mota Gomes, 1987). Patient non-adherence to medical regimens is widely acknowledged as a crucial roadblock impeding quality of care and quality of life (Bartlett, Higginbotham, Cohen-Cole, & Bird, 1990). While the physician acts as a consultant, prescribing medications, dietary, exercise and testing regimens, the ultimate success of efficacious preventative and health maintenance programs lie in the patient. Regrettably, studies have shown that the majority of patients do not follow health care regimens (Bennett Johnson, 1992; Clark & Becker, 1998; Dunbar & Stunkard, 1979; Sackett, 1976 in Clark & Becker, 1998; Sackett & Snow, 1979). The problem is not a lack of interest in health, as indicated by society's interest in health-related books, classes, medications, programs or diets that promise wellness or cure, but a general unwillingness or inability to adopt the regimens prescribed by health care professionals. Bennett Johnson (1992) points out that patients are often inadvertently nonadherent due to miscommunication, inability to recall information accurately, or deficits in knowledge/skill. Furthermore, when patients do adhere, there is no guarantee their efforts will be rewarded with control. Nonadherence translates into treatment failures which necessitate additional (often more expensive and intrusive) treatments (both medical and psychological) which ultimately results in an exponential waste of health care costs and resources (Groth-Marnat & Edkins, 1996).

The costs of nonadherence are endless. It is estimated that failing to adhere to medical regimens in the United States alone causes the country one hundred billion dollars in expenditures (Task Force for Compliance, 1993; as cited in Groth-Marnat & Edkins, 1996). These expenses are predominantly in the form of added medical bills via further treatments which are more expensive, more intrusive, and result in lost productivity (Groth-Marnat & Edkins, 1996). Inadequate observance of prescribed treatments and medical regimens is an enormous impediment to successfully living with any chronic illness. Clark and Becker (1998) estimate that only one-third of patients adhere to their physicians' medical advice. Other studies have suggested that 20 to 50 percent of patients do not show up for scheduled medical appointments and 20 to 80 percent discontinue self-change groups before they are completed (Dunbar & Stunkard, 1979; Sackett, 1976 in Clark & Becker, 1998). Bloom Cerkoney & Hart (1980) found that less than seven percent of individuals with a diagnosis of diabetes followed their self-care regimen fully. Other studies have shown this population to exhibit difficulty in adhering to dietary restrictions (Ary, Toobert, Wilson, & Glasgow, 1986; Wing, Epstein & Nowalk, 1984) and general self-care activities (Ary et. al., 1986; Watkins, Williams, Martin, Hogan & Anderson, 1967). Findings are mixed whether differences exist in reported adherence rates or reasons for nonadherence in Type 1 or Type 2 diabetes (Ary et. al., 1986; Bennett Johnson, 1992). When combined with the finding of multiple researchers that 90-98 percent of diabetes management is performed by the patient him/herself (Coonrod, Betschart, & Harris, 1994; Etzwiler, 1994) this does not hold promise for the future of diabetes self-care.

Given the preventative nature of many illnesses, both in the development of disease and in the severity of progression, noncompliance to complex medical regimens may be the most devastating obstacle to effective disease management. Studying adherence within the context of chronic diseases such as diabetes, allows researchers to investigate concerns such as medical costs, quality of care, and quality of life from a meaningful perspective. It also helps to explain the factors impacting noncompliance and subsequently provides a framework from which to have a positive effect on adherence. Rosenstock (1985) suggested three areas to influence compliance: Modifying the system, influencing the provider, and influencing the patient. The intent of this study is to investigate how patient nonadherence to a diabetic regimen can be understood and influenced from the perspective of the patient.

The word adherence elicits images of patients as either "good" or "bad" based on a unidemensional measure of compliance. Nevertheless, adherence to most medical regimens is multifaceted and individuals may be more successful in some areas of their medical regimen yet have difficulty attending to other aspects. A consistent finding in the diabetes literature has been that adherence to one area of the diabetes regimen is not necessarily correlated with self-care in other areas (Ary et. al., 1986; Glasgow, McCaul, & Schafer, 1987; Orme & Binik, 1989; Peyrot & Rubin 1994). Turk, Salovey & Litt (1986) highlight that adherence is an interactive process involving patients' cognitive structures (e.g. beliefs and meaning systems) and processes (automatic thoughts, images and coping skills), interpersonal behaviors, and the environmental consequences of these behaviors. Furthermore, multiple components are likely to influence adherence at any given time. Rosenstock (1985) proposed that situational factors such as complexity and

duration of the regimen, and the extent to which it interferes with one's lifestyle, are negatively correlated with adherence. Bennett Johnson (1992) highlights that nonadherence rates change across the different components of the regimen, across the course of the disease, and across the patient's lifetime. An individual with diabetes must make changes in all three of these arenas. Given the multidimensional structure of adherence, one can see the complexity and responsibility placed on patients to "get well".

Much of the related literature in the area of adherence research makes use of inconsistent terms to describe this construct. The reason for this may lie in the professional orientation of the researchers. For example, early studies and those coming from a biomedical perspective tended to utilize the word "compliance", denoting a patient being forced to submit to the instructions of his/her physician. The term "adherence" can be found in many of the more recent studies in the literature. This term implies a more collaborative relationship between the patient and health-care provider, however, it still implies the patient does whatever a physician orders. Even more recently, diabetes researchers have coined the terms "self-care" or "self-management" to convey the dynamic and complicated responsibilities that are associated with a multifaceted diabetes regimen and also reflect the biopsychosocial perspective (Glasgow & Anderson, 1999; Glasgow & Eakin, 1998; Goodall, & Halford, 1991; Toobert & Glasgow, 1994). Toobert and Glasgow (1994) suggest using the term self-care to describe self-care behaviors as they relate to specific areas of a diabetes regimen, and adherence or compliance to compare a patient's behaviors with medical or health recommendations.

1.1.1 Difficulties in Adherence Research

There currently exists no gold standard for adherence. As Rand and Weeks (1998) point out, factors such as the dosage necessary for therapeutic effectiveness, risks associated with nonadherence, and clinical or research goals, must be considered before setting criteria for good adherence. How adherence is defined will also depend on the instruments chosen to measure the construct. Diabetes research lacks reliable measures of adherence/self-care (McNabb, 1997). This is in part due to the complexity of the disease, in part the unreliable nature of self-report and/or physician-reported measures (McNabb, 1997) and to the lack of a common approach to quantify levels of adherence. For example, many researchers measure adherence in terms of relative frequency (e.g. never, sometimes, often, always), some with the number of times a behavior is conducted, and others calculate the percentage of time patients engage in self-care behaviors. Other problems in measuring adherence lie in the tendency to calculate a single adherence score rather than emphasize the multidimensional nature of these behaviors (McNabb, 1997).

1.2 Diabetes Mellitus

Diabetes mellitus is defined by the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus (2002) as a collection of metabolic disorders characterized by deficits in insulin secretion, insulin action, or both, which then causes hyperglycemia (abnormally high blood glucose levels greater than or equal to 140mg/dl). It has been estimated that by the year 2025, the prevalence rate of this disease in Canada and the United States will be 9.2 and 8.9%, respectively. If this is the case, this statistic

will have increased between 1.3-1.7% since the year 2000 (King, Aubert, & Herman, 1998).

It has become standard to diagnose diabetes according to any one of three methods below, with a confirmation diagnosis taken on a subsequent day.

1) Symptoms of diabetes plus causal plasma glucose concentration _ 200mg/dl. (Symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss. 'Casual' is defined as anytime of day without regard to time since last meal).

or,

2) Fasting plasma glucose (FPG) _ 126mg/dl. (Fasting is defined as 0 caloric intake for the last 8 hours).

or,

3) A 2-hr PG _ 200mg during an oral glucose-tolerance test (OGTT).

(Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2002). Chronic levels of high blood glucose are correlated with damage, malfunction, and eventual collapse of many vital organs in the body such as the eyes, kidneys, nerves, heart and blood vessels (The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2002). Side effects of hyperglycemia include increased thirst, headaches, cognitive impairment, blurred vision, frequent urination, fatigue, and/or weight loss. Other associated long-term complications of the disease put forth by the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus (2002), include retinopathy with potential loss of vision, nephropathy causing renal failure, ulcers and/or amputation of the foot and Charcot joints initiated by peripheral neuropathy,

autonomic neuropathy producing gastrointestinal, genitourinary and cardiovascular complications, as well as sexual dysfunction.

1.3 Types of Diabetes

The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus (2002) has classified diabetes mellitus into 4 distinct categories; Type 1 diabetes (formerly Insulin Dependant Diabetes Mellitus (IDDM) or juvenile diabetes), Type 2 diabetes (formerly Non Insulin Dependant Diabetes Mellitus (NIDDM) or adult onset diabetes), gestational diabetes mellitus (GDM), and other.

1.3.1 Type 1 diabetes mellitus

Type 1 diabetes is an autoimmune disorder whereby the body destroys its own ß-cells of the pancreas; the only cells that produce the insulin hormone and can regulate blood glucose levels (Centers for Disease Control and Prevention [CDC], 2002). Despite the conventional term of "juvenile-onset" diabetes, Type 1 diabetes can occur beyond the years of childhood or adolescents and can affect individuals well into adulthood. Individuals with this type of diabetes eventually become dependant on multiple daily insulin injections or an insulin pump to prevent ketoacidosis or even death. Ketoacidosis occurs when the body is lacking insulin either through an interruption in insulin treatments, an infection, or when an individual with Type 1 diabetes is first diagnosed. When the body attempts to function without the aid of insulin, it begins to utilize stored fat for energy. The burning and breaking down of fat in the body produces ketones, and the presence of ketones causes the blood to become acidic. The liver continues to produce sugars, however, without insulin; the body is unable to utilize these sugars efficiently. Subsequently, sugars continue to accumulate in the blood stream, and in

conjunction with dehydration and excess acid, ketoacidosis can become a serious problem.

The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus (2002) indicates that the rate of ß-cell destruction tends to be variable among individuals with Type 1 diabetes, however, as a rule it tends to be faster in infants and children and slower in adults. While heredity in Type 1 diabetes does not appear to have the elevated prevalence rates that are found in Type 2 diabetes, there appears to be some predisposition via genetics or environmental factors to other autoimmune disorders such as Graves' disease, Hashimoto's thyroiditis, Addison's disease, vitiligo, and pernicious anemia. Approximately 5-10 percent of all diabetes cases are found to be insulin dependant diabetes (CDC, 2002).

1.3.2 Type 2 diabetes mellitus

Type 2 is the most common type of diabetes mellitus affecting approximately 90-95 percent of diabetes cases (CDC, 2002). Both males and females are prone to develop Type 2 diabetes, however, women who have been previously diagnosed with GDM are at a higher risk of becoming insulin resistant again. Ethnicities such as African American, Hispanic/Latino American, American Indian, as well as some Asian American and Pacific Islanders also tend to be predisposed to developing this disease (CDC, 2002). Despite its reputation as an adult-onset disease, there has been a recent upsurge in the number of children and adolescents diagnosed with Type 2 diabetes (CDC, 2002).

Type 2 diabetes describes a large group of individuals who are insulin resistant or in some cases have become insulin deficient (as in Type 1 diabetes) over time. In the former case, the production-levels of insulin would be sufficient however; the insulin

secretion is defective and inadequate to compensate for the insulin resistance. This happens most often in individuals who are obese and sedentary, and increases with age. There also tends to be a very strong heredity component to type 2 which is very complex and not well understood (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2002).

1.3.3 Gestational diabetes mellitus (GDM)

GDM can be diagnosed any time after conception and represents any amount of blood glucose intolerance. Women may become hyperglycemic at any time during their pregnancy however; this usually dissipates after birth when the child, placenta, and anti-insulin related hormones are removed from the body. GDM is more common in women of Hispanic/Latino America, American Indian and African American decent. It is also more commonly found in obese women and those with a family history of diabetes (CDC, 2002). Estimates range that between 4 and 10 percent of women develop GDM over the course of their pregnancies, and of this group approximately 20-50 percent will develop NIDDM within 5-15 years of their pregnancy (CDC, 2002; Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2002).

1.3.4 Other types of diabetes mellitus

There are many other (albeit less common) reasons why diabetes may develop. This includes drug or chemical induced diabetes, infections, malnutrition, surgery, or genetic syndromes associated with diabetes. None of these circumstances *cause* diabetes per se, but may be related to the body's predisposition to resist insulin secretion. Both drugs and infection may permanently destroy ß–cells in the body and genetic syndromes such as Wolfram's syndrome are characterized by an absence of ß–cells. Other genetic

disorders such as Down's syndrome, Klinefelter's syndrome, and Turner's syndrome are characterized by chromosomal abnormalities that are correlated with an incidence of diabetes mellitus (The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2002). The prevalence rates for other types diabetes mellitus is only 1-5 percent of all cases (CDC, 2002).

1.4 Complications related to a diagnosis of diabetes mellitus

There are many concomitant medical problems associated with diabetes. Heart Disease, stroke, high blood pressure, blindness, kidney disease, nervous system disease, amputations, dental disease, complications in pregnancy, keto-acidosis and hyperosmolar (nonketotic) coma, susceptibility for other diseases such as pneumonia or influenza (CDC, 2002), and the psychological side-effects of a chronic and stressful lifestyle, all correlate to and complicate a diagnosis of diabetes. As such, treating a patient with diabetes is rarely as simple as treating the diabetes alone. Moreover, adjusting to a diabetic regimen is rarely as simple as following the guidelines set out below. Considerations must be given to drug interactions, conflicting regimens prescribed by different health care specialists for various disorders, and the psychological adjustment in coping with a plethora of medical issues.

1.5 Psychosocial aspects of Diabetes

Cox and Gonder-Frederick (1992) highlight that diabetes is one of the most psychologically and behaviorally arduous of all chronic diseases due to its demanding/ complex daily tasks as well as substantial changes in lifestyle (e.g. diet and exercise). The Expert Committee on the diagnosis and classification of diabetes mellitus (2000) suggests that the emotional and social impact of diabetes may engender significant

psychological dysfunction for both patients and family members of individuals with the disease. Furthermore, the advantages to following diabetes regimens can only be seen in the long-term (van de Laar & vand der Bijl, 2001), and quite often the only short-term results are discomfort, inconvenience, frustration and/or depression. Feifer & Tansman, (1999) reported that the prevalence rates of depression in individuals with diabetes range from 22-60%, versus 5-25% in the general population.

1.6 The Diabetic Regimen

Diabetes cannot currently be cured; therefore the goal of treatment in all cases of diabetes is simply to control blood glucose levels. While this may sound like a straightforward task, it is extremely complicated and problematic. Diabetes has been named one of the most psychologically and behaviorally demanding of all chronic diseases (Cox & Gonder-Fredrick, 1992). The Diabetes Control and Complication Trial (Diabetes Control and Complications Trial Research Group [DCCT], 1993) and the United Kingdom Prospective Diabetes Study (UK Prospective Diabetes Study Group [UKPDS], 1998) have both conducted clinical trials on type 1 and Type 2 diabetes, respectively, and concluded that intensive diabetes regimens better controlled glycemic control and decreased the incidence of diabetes-related complications. More specifically, the DCCT reported a 50-70 percent reduction in the risks for retinopathy, nephropathy, and neuropathy. Pirart (1978) found that neuropathy, retinopathy, and nephropathy were correlated with the glycemic control achieved the year preceding theses diagnoses. Given these findings, the argument for good metabolic control is unequivocally supported by the need for adherence to diabetes self-care behaviors.

The diabetes regimen extends to the outermost facets of patients' lives. Effectively living with the disease requires individuals to engage in a number of daily tasks, oftentimes repeatedly and for the duration of the patient's life. These responsibilities include daily behavioral tasks such as foot care, in addition to permanent changes in eating and exercise. Insulin monitoring and either insulin injections or pump therapy, oral hypoglycemics, a stringent and calorie controlled high fiber/ low fat pattern of eating, and regular exercise have all been found to improve glycemic control (Goodall & Halford, 1991; Ruggiero, Glasgow, Dryfoos, Rossi, Prochaska, Orleans, Prokhorov, Rossi, Greene, Reed, Kelly, Chobanian, & Johnson, 1997). The objective in following the diabetes regimen is to imitate, as closely as possible, the normal glycemic control within the body. Normal fasting level of blood glucose is 80-90 mg/dl. As the concentration of glucose rises above 100 mg/dl in a nondiabetic individual, insulin secretion also rises to compensate, and transports glucose to the major organs such as the liver, muscles and other cells. Insulin secretion systematically drops as the blood glucose naturally decreases. Goodall and Halford (1991) call attention to this already complex and interrelated procedure compounded further by the adjustments required in insulin and diet based on the level of physical exertion and/or calories consumed. For example, an individual who has exercised forcefully will need to adjust his/her insulin and diet to compensate for the increase in calorie consumption. Preventative measures, such as regular foot care, are also important components of the daily diabetes regimen. Given the complexity and multifaceted nature of the diabetes regimen alone (i.e. without addressing other medical and/or psychological complications), it is quite conceivable that adherence

to this lifestyle often falls short of what studies have shown to be optimal (e.g. DCCT, 1993; UKPDS, 1998).

Measuring adherence to the diabetic regimen is equally complex. Reasons for this may lie in the complexity of the disease itself, or as underscored by Cox and Gonder-Frederick (1992), may be a result of ambiguous regimen prescriptions given by medical professionals. Instructions such as "exercise more" or "eat healthier", are difficult to define, let alone follow and measure accurately. Diabetic self-care behaviors share the same shortcomings of adherence research in general, in so far as adherence has traditionally been measured via self-reports, which are inherently biased and subjective. Kurtz (1990) pointed out that inaccuracies in self-report data might present themselves in the form of social desirability, inaccurate recall, lack of consensus regarding units of measurement, and subtle differences in patient prescriptions.

To compensate for many of the problems highlighted above, researchers in diabetes adherence typically make use of glycated hemoglobin as an objective measure of patient self-care. Glycation levels are directly related to average blood glucose concentration in the body. Glycated hemoglobin remains in the body for approximately 100 days, and in so doing provides an independent measure of the body's average blood glucose levels for the last 2-3 months. The most commonly utilized glycated adduct of hemoglobin is A1c, or HbA1c.

The HbA1c is used as an approximate gauge of diabetic control and adherence; nevertheless, the shortcomings of this instrument are soon realized. A measure of HbA1c which is found to be high cannot specify which aspect(s) of the diabetic regimen are lacking. Glasgow and colleagues (1987) found diabetic self-care behaviors to be poorly

correlated with one another. Moreover, HbA1c levels may be influence by factors outside the boundaries of diabetic regimens. Metabolic control is a function of other variables including, but not limited to, the appropriateness of the diabetic regimen, duration of the disease, the existence of other illness, hormonal changes, economic resources, social support, heredity, anxiety, and individual responses to stress (Johnson, 1996; Lustman, Carney, & Amado, 1981; Padgett, 1991).

There has been some debate whether adherence to a diabetic regimen is a valid predictor of glycemic control. Results in the literature have been mixed, ranging from no relationship between self-reported adherence and glycemic control (Cox, Gonder-Frederick, 1992; Glasgow et. al., 1987), to a relationship between some variables (i.e. diet, blood glucose monitoring, and insulin adherence) and HbA1c by many of the same investigators (Schafer, Glasgow, McCaul & Dreher, 1983). Still others have found a strong relationship between metabolic control and dietary adherence (Brownlee-Duffeck, Peterson, Simmonds, Kilo, Goldstein, & Hoette, 1987; Christensen, Terry, Wyatt, Pechert, & Lorenz, 1983). The variability of these results could be due to the unreliable nature of self-report measures or reflect the complexity of the variables that can manipulate hemoglobin levels.

An accurate method of adherence measurement has not yet been found. Currently, the most commonly accepted means of evaluating adherence is a combination of self-report and HbA1c assays, therefore, they will both be utilized for the purposes of this study.

1.7 Cognitive-Behavioral Theories of Change and Adherence

Cognitive and Behavioral Theories have offered an enormous contribution to the explanation, modification and prediction of behaviors. Behaviorally speaking, individuals learn from reinforcing events which decrease physiological drives and activate behavior. Behaviors that avoid punishment are also learned because they reduce negative consequences set up by the punishment; this is reinforcing. The frequency of a given behavior is also determined by its reinforcements; therefore, a behavior immediately reinforced by a reward increases the probability of the behavior being repeated in the future. Cognitive theorists have highlighted the importance of subjective beliefs and expectations in learning. Behaviors are explained in terms of the perceived value of an outcome, and the subjective probability (expectation) that certain actions will have specific outcomes.

Certainly the majority of cognitive-behavioral theories put forth to explain and predict health behaviors have emphasized the importance of individual differences in adopting and maintaining behaviors. These differences have been attributed to a number of variables including vulnerability, perceived threat, motivation, and beliefs. To date, there has been little agreement regarding the most important factor(s) in behavioral change, and whether or not they interact with one another (Schwarzer, 1992). If an interaction does exist, the question then becomes *how* do they interact? Traditional diabetes education has focused on providing recipients with information, however studies have not found this approach to have the expected outcomes (Goodall & Halford, 1991; Johnson, 1996; McCaul, Glasgow, & Schafer, 1987; van de Laar & van der Bijl, 2001).

Increased knowledge does not necessarily improve self-care behaviors (Johnson, 1996; McCaul, et. al., 1987).

1.7.1 Theory of Reasoned Action

One of the most commonly cited theories of behavior is the Theory of Reasoned Action created by Ajzen and Fishbein (1980; in Clark & Becker 1998). This theory suggests that *intention* to perform behaviors is explained by a combination of *attitudes* and *perceptions*. *Attitudes* are beliefs that a particular behavior leads to certain outcomes, and *perceptions* are evaluations that these outcomes are the subjective norm (i.e. beliefs held about certain groups or people who think that one should not engage in the behavior). Intentional behavior is then considered to be a function of one's *intentions*, which are a reflection of *attitudes* toward the behavior and the *perceived social norm* (Rothman, 2000). Sociodemographic and cultural variables therefore play an important role in determining behavior according to this theory.

1.7.2 Theory of Planned Behavior

An extension of the Theory of Reasoned Action has been the Theory of Planned Behavior (Ajzen, 1991; in Clark & Becker, 1998). The Theory of Reasoned Action is described as a 'special case' of the Theory of Planned Behavior, whereby the latter is more appropriate when the probability of success due to a relative lack of control over performance is less than guaranteed. When the probability of success is guaranteed, either theory is considered appropriate. Explained briefly, the Theory of Planned Behavior postulates that *intention* is the immediate determinant of an attempt to engage in a behavior, and *subjective norms* are the second most influential determinant. As with its predecessor, this theory explains *intention* as a combination of an individual's attitudes

and the subjective norm, with the influence vacillating between these two depending on the behavior in question. *Subjective norms* are recommendations from significant others based on their approval of the behavior, and their expectation that an attempt is likely to produce the desired outcome. In summary, the Theory of Planned Behavior emphasizes the perceived probability of success and failure, normative beliefs from significant others, and motivation to comply with these beliefs (Clark & Becker, 1998).

1.7.3 Health Decision Model

The Health Decision Model (Eraker, Kirscht, & Becker, 1984; in Clark & Becker, 1998) borrowed the concepts of decision analysis, behavioral decision theory and health beliefs to create a model that addresses the health decision-making. It also addressed the inferential rules used in making medical decisions, such as tradeoffs when weighing benefits and risks, or between quality and quantity of life. The Health Decision Model emphasizes the influence of knowledge, experience, perceived efficacy of the prescribed regimen, motivation, "cues to action" with respect to the patient-physician interaction, social, and demographic variables in health decision-making and behaviors. The relationships between health behaviors and adherence behaviors are considered to be reciprocal, suggesting that they are constantly changing one another.

1.7.4 Self-Regulation Theory

Leventhal, Meyer, and Gutmann (1980; in Clark & Becker, 1998) view the individual as a scientist; formulating hypotheses regarding the physiology and causes of illness, establishing goals to cope with the problems and emotions it generates, planning actions and responses to reach his/her goals, and monitoring and appraising one's

reaction. This new information is used to adjust one's coping behaviors and set new criteria for evaluating and revising future goals.

1.7.5 Transtheoretical Model of Change

The Transtheoretical Model (TTM) proposed by James Prochaska and Carlo DiClemente (1983) postulates that individuals are continuously conducting cost-benefit analyses regarding the perceived pros and cons of changing their health behavior (a.k.a. "decisional balance"; Velicer, Prochaska, Fava, Norman, & Redding, 1998). The TTM postulates that therapeutic interventions are made most effective when they correspond accordingly with the stages of change (Prochaska & DiClemente, 1984). Interventions are designed to measure an individual's level of readiness and tailor strategies that will help the individual to move closer to making behavioral changes.

At the crux of the TTM are the following five stages, which can be identified by their various cognitive, affective and behavioral indicators (Prochaska, DiClemente & Norcross, 1992; Velicer et. al., 1998): (i) *Precontemplation,* when individuals have no intentions to change their behaviors in the near future and may be unaware or underaware of the consequences of maintaining maladaptive behaviors or may have attempted to change in the past and become discouraged with their perceived ability to change; (ii) *Contemplation,* when individuals are aware of their problem behavior and intend to change, yet despite becoming cognizant of the negative aspects of their problem behaviors, there remain highly reinforcing qualities of maintaining it; (iii) *Preparation,* during this stage, individuals have strong intentions to modify their negative behaviors and have made some unsuccessful attempts to change within the last year. Individuals have an idea of how they plan to carry out their self-adjustment; therefore they are the

group most susceptible to action-oriented programs; (iv) *Action,* where modifications made are both observable and quantifiable. Individuals are said to be in the action stage when they adequately meet the criterion agreed upon by experts that will reduce their risks of the negative heath behavior (e.g. zero cigarettes for smoking cessation); and, (v) *Maintenance* includes sustaining the desired behavioral changes and preventing relapse.

1.7.6 Social Cognitive Theory

Social Cognitive Theory (Bandura, 1977; 1982; 1986; 1997; formerly Social Learning Theory) postulates that behaviors can be predicted and explained using expectancies and incentives. Incentives are subjective values placed on an object or outcomes such as physical appearance, approval of others, economic gain, or health status. Behaviors are regulated by their consequences (reinforcements), as they are perceived by the individual. Expectancies are divided into three categories: 1) situational or environmental-outcome expectancies (i.e. how events will unfold without personal influence); 2) outcome expectancies (i.e. how one's behavior is likely to influence outcomes); and 3) self-efficacy outcomes (i.e. belief in one's own ability to perform an action to obtain the desired outcome). For example, persons valuing the perceived effects of changing their diets (incentives) will attempt change if they believe that their current diet poses threats to personally valued outcomes such as health or appearance (situational or environmental-outcome expectancies), that diet changes will reduce these threats (outcome expectancies), and that they possess the ability to adopt new dieting behaviors (self-efficacy expectations). Schwarzer (1992) highlights that both self-efficacy and outcome-expectancies influence the adoption of health behaviors, the changing of negative habits, and the maintenance of change. Outcome expectancies are

more important in forming intentions to change, while self-efficacy is crucial in intent and also executing the behavioral change.

Bandura (1977) proposed that behavior is best predicted when one considers both self-efficacy and outcome expectancies. This is especially true when engaging in new behavior(s) does not guarantee positive outcomes (1977), as in the case of diabetes where metabolic control is also a function of physiological and emotional factors. Including outcome expectancies into diabetes research may help to explain self-management behaviors. Individuals who do not adhere well may perceive the regimen to be efficacious but not believe in their own ability to carry out the required behaviors. Despite this assertion, outcome expectancies are often neglected in the literature and only a handful of researchers have included this construct into their investigations (e.g. Skelly, Marshall, Haughery, Davis, & Dunford, 1995; Williams and Bond, 2002). These limited studies have revealed some important findings. For the most part, outcome expectancies have not reached significant levels in predicting adherence on their own, however, when combined with self-efficacy Skelly and colleagues (1995) found that they predicted up to 56% of the variance in exercise adherence. Williams and Bond (2002) also found outcome expectancies did not predict a significant amount of additional variance, however, they did find some evidence to suggest that outcome expectancies moderated the role of self-efficacy and its relationship with blood glucose testing. More research is necessary to understand the relationship that outcome expectancies have on self-care behaviors.

The theory of self-efficacy postulates that one's *perceived* ability to cope with a stressful situation is an important determinant in successful adaptation (Bandura, 1986).

Perceived self-efficacy is the belief in one's abilities to "organize and execute the courses of action required to produce [a given goal]" (Bandura, 1997, pg.3). These are not necessarily limited to behavioral interventions. Regulating one's thought processes, motivation, or affective states as well as changing environmental conditions and finally, one's actions, all influence a situation (Bandura, 1997). Moreover, self-efficacy theory proposes that beliefs in one's ability to perform certain behaviors influence: (a) their choice of behavior and the situations that will subsequently be avoided or attempted; (b) the effort put forth towards a task; (c) the length of time spent on a task; and (d) one's emotional reaction to the threat of failure (Johnson, 1996).

Individuals develop their sense of self-efficacy based on four hierarchically ordered sources of information: performance accomplishments, vicarious learning, verbal persuasion, and physiological states. Experiences of success (performance accomplishments) are the most influential way to develop strong efficacy. Negative experiences disrupt feelings of self-efficacy, especially when they are experienced early in the learning/change process. Rapid successes are most beneficial to a strong sense of self-efficacy, which is especially challenging when facing a complicated diabetes regimen. Vicarious learning occurs when individuals observe others and learn via modeling. Comparability of models is based on similar personal characteristics and shared experiences. In the case of managing diabetes self-care behaviors, this would be someone with a similar regimen who encounters similar obstacles. The third source, and the most commonly used vehicle of enhancing efficacy, is verbal persuasion (van de Laar & van der Bijl, 2001). This source tends to be only as effective as the recipient's confidence in the person who offered it. Reliability of the source is based on expertise,

credibility, and attractiveness. Lastly, individuals who assess their physiological and emotional state in a negative, tend to have lower self-efficacious thoughts. Physical symptoms can be interpreted as indicators of personal ineffectiveness, which negate self-efficacy.

1.7.6.1 Multidimensionality of Self-Efficacy

Bandura (1997) theorized that beliefs of efficacy vary on several dimensions. First, efficacy beliefs vary in their *level*. The level of self-efficacy influences not only the choice to attend to a situation, but also how much effort is exerted, the length of perseverance in the face of adversity (Coyne & Smith, 1994), whether cognitions help or hinder, how much stress and depression is experienced in dealing with the situation, and the level of accomplishment realized (Bandura, 1997). Efficacy can also vary in its *generality*. Self-efficacy has been misunderstood as "specific behaviors in specific situations" (Bandura, 1997, pg. 49), however individuals may see themselves as efficacious across a variety of activities or perhaps only in limited areas. Generality of efficacious beliefs to similar situations is important because lacking it, individuals would be forced to establish new efficacy beliefs for every activity that has any element of novelty. However, self-efficacy is very situation-specific, and as such should be seen as a specific state, not a generalized trait (Lorig, Chastain, Ung, Shoor, & Holman, 1989). Lastly, self-efficacy can vary in *strength*. Weak efficacy is more likely to be negated by disconfirming situations, whereas stronger efficacy tends to persevere in the face of adversity.

1.7.6.2 Self-Efficacy and Health Behaviors

Self-efficacy has intuitive appeal when investigating negative health behaviors

because of its emphasis on change. Bandura (1986) suggests that self-efficacy is the strongest predictor of behavioral change. When applying social cognitive theory to personal change (e.g. health promoting or defeating behaviors), Bandura (1997) suggests a three-fold processes. Individuals begin by implementing new behavioral patterns. This is followed by generalizing their behavior to unfamiliar situations and eventually to maintaining the behavior over time. Self-efficacious beliefs are important at each of these stages as indicated by both cross-sectional and longitudinal research (Kavanagh, Gooley, & Wilson, 1993; Johnston-Brooks, Lewis & Garg, 2002; McCaul et. al., 1987; Talbot, Nouwen, Gingras, Gosselin, & Audet, 1997). For example, individuals will not contemplate change if they do not have belief in their ability to do so (Bandura, 1997). Brod & Hall (1984) found that smokers who did not believe in their ability to quit smoking never attempted smoking cessation. Maintaining motivation to continue new behaviors despite set backs also requires high levels of self-efficacy. For individuals with chronic and complicated health regimens such as diabetes, this can be an arduous task. As such, efficacy beliefs have been found to play an important role in adherence to medical treatments in general (Goldberg, 1996; Lev, 1997; O'Leary, 1985) and to diabetic regimens in particular (Hurley & Shea, 1992; Johnston-Brooks et al., 2002; Kavanagh et. al., 1993; Rosenstock, 1985; Talbot et. al., 1997; van de Laar & van der Bijl, 2001; Williams & Bond, 2002). Padgett, Mumford, Hynes, and Carter (1988) conducted a meta-analysis of published and unpublished studies on educational and psychosocial interventions of persons with diabetes mellitus. The authors concluded that studies utilizing social cognitive theory had the most favorable results. Rosenstock (1985) and Johnson (1996) both suggested that self-efficacy should be included in the design of all

educational programs for patients with a diagnosis of diabetes mellitus.

Johnston-Brooks et. al. (2002) investigated self-efficacious beliefs as they related to the self-care and glucose control of 88 adolescents with Type 1 diabetes. Longitudinal analysis revealed that self-efficacious beliefs in the ability to adhere to a self-care regimen as measured by the Summary of Diabetes Self-Care Activities Questionnaire was the best predictor of better self-care as well as glucose control (as measured by $HbA1_c$) at 3, 6 and 9-month follow-up. The study also found mediating variables. Longitudinally, diet self-care mediated the relationship between self-efficacy and glucose control. Cross-sectionally, self-efficacy predicted general and testing self-care, which then predicted $HbA1_c$. These findings are important because although this model has been assumed for some time, there is little empirical evidence for its existence.

In their now widely cited study of self-efficacy and adherence to diabetic regimens, Kavanagh and colleagues (1993) investigated the ability of efficacy levels to predict self-care behaviors over a period of 2 months. The investigators wanted to control for the effects of past behaviors when measuring the relationship between self-efficacy and self-care behaviors. Participants completed measures of general health, self-efficacy, treatment adherence and mood. Glycemic control was assessed via the standard glycosylated hemoglobin assays (HbA_1c). The investigators were interested in understanding whether adherence at T_2 would be better predicted by T_1 reports of efficacy or by self-reported adherence. Their analysis revealed that self-efficacy was the most powerful predictor of future adherence in the areas of diet and exercise, averaging 33% of the variance. This was found to be even stronger than negative emotions or previous adherence 8 weeks earlier. This study is significant to self-efficacy literature because it is

one of the earlier studies to demonstrate that efficacy affects future diabetic self-care behaviors. Moreover, it found that self-efficacy is actually stronger than past behaviors in predicting future behaviors.

In an attempt to explore the continual finding that self-efficacy is associated with self-care behaviors but poorly related to physiological variables (e.g. glycemic control), Padgett (1991) conducted a cross-cultural study of self-efficacy and its relationship with other variables. Specifically, Padgett's study included 147 Croatian diabetic patients residing in Zagreb, who were given instruments measuring the variables of self-efficacy, depression, and adherence. She also collected physician-rated adherence measures and gathered information regarding HbA1c from patient medical records. As expected, the researcher found self-efficacy to be moderately, but significantly related to measures of adherence, both for respondents and physicians. There was also a relationship found between self-reported measures of depression and self-efficacy. This relationship has been highlighted by Bandura (1977) and may reflect feelings of hopelessness when faced with the continued inability to achieve valued outcomes (Padgett, 1991). Conversely, the analysis found weak to almost nonexistent relationships between HbA1c and adherence and self-efficacy. Padgett underscored the complexity of potential predictors on metabolic control and emphasized the need for prospective designs and multivariate causal models to account for main and interaction effects among these variables.

In 1992, Hurley and Shea attempted to demonstrate the necessity of including self-efficacy training into diabetes education. The investigators sampled 142 adults, ages 18-73 years with Type 1 and Type 2 diabetes who were receiving intensive inpatient care to gain metabolic control. Participants were given a measure of self-efficacy prior to

discharge from the hospital. Three weeks later, participants were mailed the followed up measure of self-care. Demographic information was obtained from patient medical charts during the 5-day hospitalization. The analysis revealed that patients had relatively high efficacy upon discharge from the hospital, and that these scored accounted for 33% of the variance in self-care behaviors 3 weeks later. The authors further revealed via multiple regression analyses, that once the variance of self-efficacy on self-care behaviors had been considered, none of the demographic variables of age, gender, or diabetes complications revealed statistically significant predictor variables.

Given the comprehensive research in the diabetes/self-efficacy field, McCaul and colleagues (1987) dissected the construct of self-efficacy to its fundamental components and extended this to the research in diabetes and regimen adherence. The investigators looked at four categories of self-efficacy; knowledge, expectancies, skills, and environmental support. Both adults and adolescents with insulin dependant diabetes were given multi-modal (e.g. self-report, self-monitoring, mechanical, and collateral) measures of the aforementioned predictor variables as well as multiple measures of adherence. These measures were taken again approximately 6 months later. The authors concluded that expectancies played the largest predictive role for both adolescents and adults in predicting both current and future adherence. Still significantly related, albeit less than expectancies, was the relationship between environmental support and adherence for both age groups. Only adolescents were found to be significantly affected by diabetes-related skills (especially in the area of insulin injections), perhaps as the authors point out, because of the extended period of time that adults may have had to adjust to the diagnosis. Knowledge was found to be unrelated to adherence for adolescents and

inconsistently related for adults (i.e. it predicted only current but not future glucose-testing and dietary adherence). These findings suggest the need for additional research to assist in understanding the role outcome expectancies play in self-efficacy.

Williams and Bond (2002) also investigated the impact of self-efficacy to include outcome expectancies on self-care behaviors. The investigators measured self-care using two measures, and self-efficacy, outcome expectancies and social support using one measure for each construct, respectively. Self-efficacy was found to predict diet , exercise self-care and blood glucose testing, sharing an average of 26.2% of the variance. Outcome expectancies were found to moderate the relationship between efficacy and self-care, however, when self-efficacy was statistically controlled, outcome expectancies were no longer significantly related to adherence. The conclusion that self-efficacy predicts self-care is consistent with previous investigations (Glasgow, et. al., 1987; Hurley & Shea, 1992; Johnson, 1996; Johnston-Brooks et. al., 2002; Talbot, et. al., 1997; Padgett, 1991; van de Laar & van der Bijl, 2001; Williams & Bond, 2002). The distinctive finding in this study was the conditional relationship that outcome expectancies had on self-care. Outcome expectancies predicted an average of 10% of the variance of self-care behaviors, however, when self-care was regressed on both outcome expectancies and self-efficacy, it was no longer significant. The clinical implications from this study are widespread because they suggest an explanation for the lack of association often found between diabetes knowledge and diabetes self-care behaviors (Johnson, 1996; McCaul et. al., 1987; van de Laar & van der Bijl, 2001). Patients who believe that diabetes self-care behaviours will lead to desired positive outcomes but lack the belief in their ability to carry out these behaviors, will certainly not be found to be high in adherence.

1.7.7 The Health Belief Model

The Health Belief Model (HBM; Becker, 1974, as cited in Janz & Becker, 1984; Rosenstock, 1985; Kirscht, 1974; Rosenstock et. al., 1988) was first created by the U.S. Public Health Service to predict and understand the lack of participation in preventative programs for individuals at risk for developing medical illnesses. Kirscht (1974) later applied the theory to individual responses to medical symptoms, and Becker (1974) applied it to the study of patients following medical regimens. The HBM assumes that decisions regarding health behavior are based on rational thinking (Schwarzer, 1992). The foundations of the model lie in value-expectancy theory, or the value that an individual places on a given condition and the estimated likelihood that the goal can be achieved (Clark & Becker, 1998). When relating the HBM to health-related behaviors, this translates into the value an individual places on getting well (or avoiding illness) and the belief that specific behavior(s) will alleviate (or prevent) the unwanted condition. The theory proposes that individuals will engage in preventative behaviors if they believe that they are at risk (*susceptibility*), believe the disease to be dangerous (*severity*), believe that they can avoid the disease via the preventative regimen (*benefits*), and believe that the benefits overshadow the costs of engaging in the new regimen (*barriers*). Furthermore, stimuli or *cues to action* must be present in the environment to trigger this decision-making process. Perceived susceptibility and perceived severity of disease result in the experience of threat, which is modified by demographic, interpersonal, social, and structural variables insofar as they influence one's motivation and perceptions about change (Clark & Becker, 1998). These health belief elements have also been reformulated to include individuals with a medically established illness, whereby *perceived susceptibility* includes acceptance of the disease, perceived estimates of resusceptability, and susceptibility to other diseases;

perceived severity includes subjective values of seriousness if the disease is left untreated (both physically and socially); *perceived benefits* suggests the advantage(s) of following the medical regimen; and *perceived barriers* highlight the unpleasant, inconvenient, or time-consuming aspects of following a medical regimen (Rosenstock, 1990). Janz and Becker (1984) reviewed the findings of 46 HBM-related investigations (18 prospective and 28 retrospective) and found *barriers* to be the most significantly related dimension (89%) to the health behaviors under investigation. This was followed by *susceptibility* (81%), *benefits* (78%), and *severity* (65%).

Bloom Cerkoney and Hart (1980) tested the ability of the HBM to predict patient level of adherence 6-12 months after receiving diabetes education classes at a community hospital. Thirty patients with both Type 1 and Type 2 diabetes mellitus were interviewed in their homes and queried about their health beliefs, levels of adherence and general demographic information. Additionally, self-report and direct observation methods were used to collect data regarding adherence with insulin administration, hypoglycemia, urine testing, and foot care. Self-report was used to measure adherence to diet and health beliefs. The investigators found that the HBM was able to account for 25% of the variation in the adherence of this sample. Given the educative classes that these individuals participated in 6-12 months earlier, the authors point out that a "much higher level of correlation between these variables would be necessary to be able to use these [health belief] motivators as reliable clinical predictors." (pg. 597; Bloom Cerkoney & Hart, 1980). Despite these lower than expected findings, the study did reveal that perceived severity was the strongest subscale in predicting adherence, accounting for approximately 16% of the variance.

In 1985, Harris and Linn investigated the HBM in a sample of 93 middle-lower to lower-class male patients with an average age of 53 years, all whom had Type 2 diabetes. The Diabetes Health Belief Scale (DHBS) was designed by the authors (Harris, Linn, Skyler, & Sandifer, 1987) to measure the four areas of health beliefs outlined by the HBM, as well as one subscale to measure patient understanding and family support, and one general health motivation scale. Patients provided a self-report measure of health beliefs (DHBS) which was followed by self-report, nurses' report, and laboratory instruments of both short and long term measures of adherence (i.e. 24-hour urine fasting blood glucose, fasting triglyceride, and glycosylated hemoglobin) six weeks later. The investigators found the HBM as measured by the DHBS to predict 11% of the variance in adherence; however, this finding was predominately due to the influence of the perceived severity subscale, which predicted 8% of the variance alone. The other three percent of this instrument's predictive value lie in perceived susceptibility (1%), perceived psychological barriers (1%), and perceived benefits to treatment (1%), which did not add significantly to the measure's overall predictive ability. Similar to other findings (e.g. Bloom Cerkoney & Hart, 1980; Bond, Aiken, & Sommerville, 1992; Glasgow, et. al., 1986; Ruggiero, et. al., 1997; Tootbert & Glasgow, 1994; Williams & Bond, 2002), the researchers found these men to be adhering best to the "medical aspects" of their regimen (taking medications, urine testing) and least adherent in the areas of diet and exercise. Surprisingly, the HBM was better able to predict metabolic control (which incidentally was found to be poor in both short and long term measures) than adherence (i.e. 23% vs. 11%). This is contrary to similar studies (Bond, et. al., 1992; Brownlee-Duffeck, et. al.,

1987), which have found the HBM to be a better predictor of adherence, not metabolic control.

Brownlee-Duffeck and colleagues (1987) tested the predictive ability of the HBM in 143 patients with Type 1 diabetes. Participants ranged in age from 13-64 years, and were given the Diabetes Health Belief Questionnaire (DHBQ), an instrument designed to measure the four components of the health beliefs model. The researchers found that health beliefs were a better predictor of self-reported adherence than they were in predicting metabolic control (GHb), with the former predicting 41-52% of the variance, and the latter predicting 19-20% of the variance. This finding is consistent with other literature which has found metabolic control to be poorly associated with health beliefs (Bond, et. al., 1992; Harris & Linn, 1985). As predicted, perceived severity and benefits were correlated with higher self-reported adherence, and perceived costs were associated with poorer adherence and metabolic control. However, contrary to the assumptions of the HBM, greater perceived susceptibility to diabetes-related complications was associated with poorer metabolic control.

Bond, Aiken & Somerville (1992) tested the effectiveness of the HBM to predict self-care behaviors in a sample of 56 adolescents with Type I diabetes. The researchers used both the Diabetes Health Belief Scale (DHBS) and the Diabetes Health Belief Questionnaire (DHBQ) mentioned above, as well as the Barriers to Adherence Questionnaire to measure health beliefs, and structured interviews, parental questionnaires, and HbA1c levels to measure adherence. They found the highest rate of self-management to be attained with low perceived threat and high perceived benefits-costs. Threat tended to interact with benefits-costs in predicting compliance, and with

cues in predicting metabolic control. The most variance the HBM was able to predict was almost 7% on a self-report measure of adherence.

1.7.7.1 Limitations and criticisms of the HBM

Janz and Becker (1984) have emphasized that the HBM is a psychosocial model and as such, it is not intended or able to account for variance in individual behaviors which are not related to attitudes and/or beliefs. For example, the authors suggest that other influences such as the habitual nature of some health behaviors (e.g. smoking or eating) may preclude the cognitive decision-making process. They draw attention to the fact that many individuals may initiate behaviors for reasons that are not health related (e.g. loosing weight to appear more attractive, smoking cessation for social approval), and that economic or situational factors may prevent individuals from engaging in behaviors despite its intuitive appeal. Lastly, the authors highlight that the HBM model assumes that "health" is globally valued and cues to action are prevalent in the environment. The HBM has undergone substantial criticism (e.g. Harris & Linn, 1985; Schwarzer, 1992) on many levels, perhaps the most salient being its absence of cognitive mediators such as self-efficacy in its prediction of health behaviors (Schwarzer, 1992). In response to these criticisms, Rosenstock and colleagues (1988; Strecher, McEvoy, DeVellis, Becker & Rosenstock, 1986) have addressed these and other shortcomings within the model. The authors have reported that the HBM has many similarities as self-efficacy. They have drawn parallels between situation-outcome expectancy and the combination of perceived threat and severity of illness. They have also highlighted similarities between outcome expectancies with perceived benefits. While they report that the "HBM has ignored efficacy expectations (in the Bandurian definition) and thus

may have failed to account for as much variance in behavior as it might" (pg. 179; Rosenstock et. al., 1988), self-efficacy has only been incorporated into the model insofar as stating that it has been empirically shown to predict health behavior and should be considered in the HBM.

1.8 Justification for this study

The goal of the present investigation is to predict the multidimensional medical and behavioral self-care behaviors of individuals with a diagnosis of Type 1 diabetes. Rather than forcing participants into a dichotomy (i.e. either adherent or nonadherent to their entire diabetes regimen), this study anticipates that some areas of the regimen will be more closely followed than others (Ary et. al., 1986; Glasgow et. al., 1987; Johnson, 1996; Schafer et. al., 1983). Most importantly, this research aims to determine how self-care behaviors can best be predicted using the Health Belief Model, a widely utilised theory of patient adherence. Although the HBM has been used extensively in adherence research, its predictability has been found to be limited. A review of the literature suggests "lower than expected" predictability of the original Health Belief Model (pg. 182; Rosenstock et. al., 1988). Given these criticisms and the revisions that have been suggested for the HBM, coupled with the relatively consistent predictive ability of self-efficacy in health behavioral change, it is hypothesized that the original HBM is lacking a critical element of self-evaluation which can be found in self-efficacy theory. Many HBM theorists (e.g. Rosenstock, 1985; Rosenstock et. al., 1988; Strecher et. al., 1986) have made recommendations to add self-efficacy to the original HBM and investigate its new predictive strength. Indeed, a review of the literature revealed that in the few studies to have done so, self-efficacy has been shown to relate to stricter adherence (Aalto &

Uutela, 1997; Clark, Rosenstock, Hassan, Evans, Wasilewski, Feldman, & Mellins, 1988; Kavanagh, Cooley, & Wilson, 1993; McCaul et. al., 1987; Wilson, 1993).

Clark and colleagues (1988) conducted a study investigating the management of childhood asthma with the theory of self-efficacy and aspects of the HBM (specifically, perceived severity). The investigators found self-efficacy to be able to account for only 3% of the variance related to adherence, and unlike previous research, perceived severity was not a useful predictor of disease management. Generalizations regarding the usefulness of self-efficacy and HBM to predict self care behaviors based on this study should be made with caution. Firstly, the authors did not include the entire Health Belief Model, but rather a single component. For a theory to be useful, it must be used in its entirety. Secondly, the authors themselves cast a dubious impression on the criterion validity of their measure of self-efficacy, suggesting that it may have been a better measure of locus of control. Lastly, this study investigated the self-management of children with a diagnosis of asthma and should be interpreted cautiously when speaking to an adult population of Type 1diabetes.

Aalto and Uutela (1997) attempted to augment the HBM by including several elements of self-evaluation (locus of control, self efficacy, health value, and social support) in their investigation of adults with Type 1 diabetes. The researchers found that this "Extended HBM" (EHBM) explained 14% of the variance relating to a diabetic diet, and 21% of the variance related to self-monitoring of blood glucose. Of specific interest to the current investigation were the results pertaining to self efficacy indicating that self efficacy in self monitoring (of blood glucose levels) was associated with perceived higher net benefits of self monitoring and an actual increase in frequency of self monitoring,

conversely, it was not the cognitive component of self efficacy, but rather perceived social support that was correlated with dietary adherence.

Given the limited number of empirical studies supporting the benefits of incorporating self-efficacy into the HBM as a predictive theory of health behaviors, this study attempts to add to the literature and predicts that including self-efficacy will address a self-evaluative component that the HBM is lacking, thereby adding to its predictive strength. Based on this premise and the literature reviewed thus far, the following hypotheses are offered:

H1: That self-care behaviors will not be correlated amongst themselves, but rather, some regimen areas will be better adhered to than others (Ary et. al., 1986; Glasgow, et. al., 1987; Orme & Binik, 1989; Peyrot & Rubin 1994).

H2: That the ability of the HBM to predict self-care behaviors will be improved by adding a self-evaluative component, via self-efficacy adherence (Aalto & Uutela, 1997; Clark, Rosenstock, Hassan, Evans, Wasilewski, Feldman, & Mellins, 1988; Kavanagh, Cooley, & Wilson, 1993; McCaul et. al., 1987; Wilson, 1993).

Theoretical and empirical explanations will be discussed as they relate to these findings.

CHAPTER 2: METHODS AND TEST PROCEDURES

2.1 Participants

Outpatients were recruited from a privately owned diabetes clinic. Studies have repeatedly found that individuals at different developmental stages (associated with different cognitive and social capabilities) adhere differently to diabetes self-management behaviors (e.g. Bennett Johnson, 1992; Brownlee-Duffeck et. al., 1987; Goodall &

Halford, 1991; Williams & Bond, 2002). For example, young children are often unable to administer insulin or test glucose, and adolescents are often influenced by peers which have been found to have detrimental effects of adherence (Johnson, 1996). Therefore, to decrease the potential of confounding variables affecting self-care, individuals in this study wee excluded if they were not 18 years of age or older. To allow for initial adjustment, stabilization of the disease, and development of self-care behaviors, participants were only eligible for inclusion into this study if they had diabetes for at least 1 year. Furthermore, to control for the potential effects of confounding variables on one's diabetes regimen, patients were also excluded if they currently had a major medical complication related to diabetes (e.g. incapacitating renal or cardiovascular problems) or a major psychiatric disorder (e.g. schizophrenia, personality disorders, substance abuse). Individuals with a diagnosis of Type 1 or 2 diabetes mellitus were permitted to participate. For those individuals requiring insulin, participants were considered eligible regardless of the means of insulin administration (e.g. pump users and insulin injectors). Of the one hundred and fifty-six patients who agreed to participate in the study, 122 questionnaires were returned, however, only 118 were complete and met all the inclusion criteria. An additional 46 individuals were not approached because they did not meet the minimum age criteria, one individual who was approached did not meet the medical criteria, and another patient simply refused to participate.

2.2 Procedure

Individuals were given the opportunity to participate in this study during a routine intake assessment. Patients were asked to respond to a questionnaire that took approximately 20-30 minutes to complete. To avoid the effects of social desirability, the

study was introduced as an investigation into the thoughts and beliefs of individuals with diabetes. After receiving informed consent (see Appendix A) patients were asked to complete the measures either in the waiting area or at home (and provided with a self-addressed stamped envelope). When available, hemoglobin A1c was assessed by review of the patient's medical records.

2.3 Measures

In addition to the theoretical hypotheses stated above, this study attempted to put emphasis on some important methodological considerations. Glasgow et. al. (1987) and Bennett Johnson (1992) both emphasize that a single measure may fail to capture the complexity of adherence behaviors, therefore, multiple modalities were used in measuring dependant variables. These included self-report and biochemical measures of hemoglobin. In addressing the multidimensional nature of adherence highlighted by Orme & Binik (1989) and Peyrot & Rubin (1994) and discussed earlier, this study investigates four distinct areas of self-care; diet, exercise, medication taking, and blood glucose testing.

The questionnaires completed by participants in this study included a series of self-report instruments which took approximately 30 minutes to complete. They included one demographic form, a measure of self-efficacy, a measure of health beliefs, and two measures of adherence (1 self report measure and one biologically-based measure). Questionnaires included the following: A general demographic questionnaire (created for the purposes of this study), The Activities Questionnaire (McCaul et. al., 1987), the Diabetes Health Belief Questionnaire (DHBQ; Brownlee-Duffeck, et. al., 1987), and the Summary of Diabetes Self-Care Activities (SDSCA; Toobert & Glasgow, 1994). As

mentioned earlier, the diabetes literature has not received substantial attention since the 1980's/early 1990's. Questionnaires created for the purposes of psychosocial research have not kept up with advances made in diabetic technology. As a result, many of the highly respected measures found in the literature have become outdated. The questionnaires highlighted above were chosen on the basis of their psychometric properties and wide usage in the literature; however, some revisions were necessary to make them applicable to diabetes care today. A brief description of each of these measures follows and copies of the revised measures can be found in Appendix A. Lastly, valid hemoglobin A1c (HbA1c) was attained via medical records when available.

2.3.1 Demographic Information

Demographic information was collected in an attempt to control for many of the possible confounding variables that have been found to affect adherence generally, and metabolic control specifically. A questionnaire was created for the purposes of this study, and queried participants in the areas of age, gender, socioeconomic status, years since diagnosis of diabetes, type of diabetes, specific areas of prescribed self-management (e.g. diet, exercise, oral medications, and insulin testing), concomitant diabetes complications, and history of psychological services and diabetes education.

2.3.2 Measure of Self-Efficacy

The Activities Questionnaire (McCaul et. al., 1987) is a 29-item self-report measure of patients' confidence in their ability to perform a graded series of diabetes-related regimen behaviors. Participants rate their perceived ability to perform behaviors in four areas of self-care (e.g. glucose testing, exercise, eating habits, and medication taking) on a 200-point likert scale ranging from "*completely certain that I could not*" to

"*completely certain that I could*". Items in the self-care areas of eating habits, and exercise were updated for the purposes of this study (e.g. changing sugar and high fat monitoring to carbohydrate and caloric monitoring where appropriate). Scores were standardized and then averaged to form a composite score in each of the four areas of self-care.

2.3.3 Measure of Health Belief

Brownlee-Duffeck and colleagues (1987) created the Diabetes Health Belief Questionnaire (DHBQ) to test the HBM in individuals with diabetes. The 27-item questionnaire assesses perceived severity of diabetes and its complications, perceived susceptibility to diabetic complications, perceived benefits of adhering to self-care behaviors, perceived costs of adherences, and cues for adherence. Individuals respond to each question on a 5-point likert scale. Brownlee-Duffeck found internal reliability estimates for each of the 5 subscales to be as follows: severity, .66; susceptibility, .73; benefits, .78; costs, .73; and cues to action, .10. The authors highlight that these subscales were conceptually, rather than empirically constructed.

Only one item was removed from the original scale ("Having to test my urine is…") due to its inapplicability to current diabetic testing protocols. Composites for each of the 5 areas of health belief were calculated by first standardizing raw scores, then averaging scores for each area.

2.3.4 Measures of Adherence

Literature on adherence to diabetic regimens has typically focused on four areas of self-care: diet, exercise, blood glucose testing, and medication taking. Research on the dietary behaviors of IDDM patients have shown that as many as 60-75% fail to eat

the prescribed types or amounts of food, with fat consumption being too high and carbohydrates too infrequently consumed (Johnson, 1996). In diabetic regimens, timing and frequency of meals is as important as the type of foods (Bennett Johnson, 1992). Ary and colleagues (1986) found that patients with Type 1 diabetes adhered to prescribed exercise regimens only about one-third (31%) of the time. Johnson (1996) points out that prevalence rates in the area of blood or urine glucose testing varies with different methods of measurement. In a review of the literature, she found that 36-82% of patients fail to regularly test their blood/urine glucose, and as many as 34% fail to test at all. Contrary to the diet and exercise components of self-care, Ary and colleagues (1986) found that medication taking was the best adhered to area of diabetic regimens.

2.3.3.1 The Summary of Diabetes Self-Care Activities (SDSCA)

A well-cited instrument in measuring self-care behaviors in diabetes research is the SDSCA (Toobert & Glasgow, 1994). This 12-item measure was created to provide brief indices of self-care behaviors in different areas of a diabetes regimen. The measure can be used in both clinical and research venues. Individuals are probed on the percentage (increasing by intervals of 25) of time spent in various activities under the spheres of diet, exercise, glucose testing and medication taking. Patients report how well they have followed their regimen within the last seven days. Self-care was assumed by these researchers to be a variable construct, thus a seven-day recall period was chosen to establish stability. The investigators determined that recall any longer than this period may introduce error in the form of inaccurate recollections (Toobert & Glasgow, 1994; Toobert, Hampson & Glasgow, 2000).

The SDSCA had to be updated on all four areas of diabetes self-care, therefore the psychometric properties reported by the authors were no longer considered appropriate for the revised measure. The SDSCA is traditionally scored by taking the raw score from each area of self-care and converting it to a standardized score with a mean of zero and a standard deviation of 1. The standardized scores are then averaged to form a composite score for each area, thereby giving items with different scales equal weighting.

2.3.3.2 Hemoglobin A1c

Hemoglobin A1c (HbA1c) was used as an indirect measure of adherence. Non-diabetic HbA1c values range from 3.1-6.1%, however it is unrealistic for an individual with diabetes mellitus to maintain these values without being at risk for hypoglycemic shock (Johnson, Freund, Silverstein, Hansen & Malone, 1990). Goldstein and colleagues (Goldstein, Parker, England, Weidmeyer, Rawlings, Hess, Little, Simonds, & Breyfogle, 1982) suggested that an HbA1c of 9.0% or less is an acceptable level for individuals with diabetes mellitus. There is controversy in the literature regarding the efficacy of HbA1c values as a measure of adherence; however, it has been shown to be a reliable measure of long-term metabolic control, which is presumably influenced by the diabetic regimen. While the literature has found the relationship between self-care behaviors and HbA1c to be weak, glycemic control is still the ultimate goal of adherence research and should therefore be included as a criterion variable. Bennett Johnson (1992) points out that if the purpose of adherence research is to positively impact the patient's medical condition, then biological outcomes should be examined. Johnson (1996) points out that if the point of adherence literature is to improve patient medical condition, then patient behavior should be examined within the context of biological outcomes. The most widely

accepted method of assessing adherence, including the well known Diabetes Control and Complications Trials funded by the National Institute of Health (e.g. DCCT Research Group, 1993), has been to combine self-report measures with $HbA1_c$ levels.

This study also aimed to obtain an additional measure of adherence by downloading glucometer results and calculating a "% on target" score. However, of the patients who participated in this study, very few had downloaded their glucometers on the day of their appointment, and this measure of adherence was subsequently discarded.

2.4 Results

Analysis were conducted using the SPSS-Student Version 12.0 statistical package and are summarized in four sections. First, demographic statistics are reported, including those used for the individual predictor variables. Secondly, five multiple regressions are presented for each area of adherence. Diagnostics are reviewed next, with special attention given to power. Lastly, violations of assumptions were explored in detail.

Demographic Variables

Table 1 provides a demographic overview for this sample. The final sample included 46 males and 72 females, of whom 89% were Caucasian, with an average age of 44 years (range=18 to 73). In general, the sample was of middle to high socioeconomic status. For example, 56 % had a bachelors or post graduate degree and 52% made from $41-100,000+/annum. Most participants were employed full time outside the home (53%) and 50% were currently married. This statistic was lowed by the small number of school-aged participants (15%) who were involved in this study.

The average number of years since diagnosis of diabetes was 21 (range= 1 to 58), which was inflated by the fact that the majority of the patients (69%) had Type 1 diabetes.

Furthermore, 69% of the patients at this site used continuous subcontaneous pumps for insulin administration. The participants in this study were followed closely primarily by endocrinologists (77%) whom they had for the most part seen within the 3 months of participating in this study (77%). Furthermore, 45% of individuals had seen a diabetes educator 4-6 times in the last twelve months. Related to mental health, a relatively small number of participants were currently receiving psychological services (11%), and 24% of the individuals who had ever received psychological services stated that their problems were not diabetes-related.

Insert Table 1 about here

Statistical Analyses

A series of hierarchical multiple regression analyses were performed to evaluate the relationship between the predictor variables and the five dependant variables: four self-reported adherence composites in the areas of exercise, diet, glucose testing and medication taking, and the indirect measure of glycemic control (i.e. HbA1c). In all five analyses, age, gender, and duration of diabetes were treated as control variables and entered into the equations first. The five subscales of the DHBQ (i.e. severity, susceptibility, costs, benefits, and cues to action) were then entered simultaneously into

each regression equation, and the four composite scores of self-efficacy (i.e. diet, exercise, glucose testing and medication taking) were entered last. Summaries of all five regressions are presented in Tables 2-6.

Insert Tables 2-6 about here

For the multiple regression conducted with dietary adherence as the dependant variable, demographic variables accounted for only 2% of the variance when entered alone into the equation. When the HBM was entered, the model accounted for 7% of the variance in dietary adherence (R^2 change=.05). Lastly, when SE was entered into the equation last, it improved only to 11% of the variance being predictable (R^2 change=.04). Table 2 illustrates a summary of the regression. The regression model for adherence to exercise regimens is presented in Table 3. Predictor variables were entered in the same order as those listed above. Coefficient of determination (R^2) was 0.091 for HBM and 0.167 for SE, indicating that these variables explained 9 and 16 percent of the variance in exercise adherence, respectively. For glucose testing, demographic variables were found to account for a small but significant percentage of variance in adherence, $F(3,114)=2.81$; $R^2=.07$, $p<.05$. When HBM was entered into the analysis, it did not account for a significant increase in the change in predictability, R^2 change=.04, $F(5, 109)=.99$; $p>.05$. Similarly, when SE was entered, there was no significant change in adherence predictability, R^2 change=.02, $F(4, 105)=.57$; $p>.05$. This regression model can be found in Table 4.

The regression for adherence to medication taking was a poor fit (adjusted R^2 =-.001, -.002, and -.022 for demographic variables, HBM, and SE, respectively). Likewise, the overall relationship was not found to be significant for any of the independent variables. For demographic variables, $F(3, 114)=.04$, $p>.05$; for HBM, $F(5, 109)=.99$, $p>.05$; and for SE, $F(4, 105)=.46$, $p>.05$. These statistics can be found in Table 5.

The fifth and final regression was conducted with hemoglobin A1c as the criterion variable. Despite studies that have continuously shown a poor relationship between diabetes self-care and HbA1c, this measure was included on the premise that the ultimate goal of diabetes self-care is metabolic control. Unfortunately, only about ½ of the current sample had updated (i.e. within the last 90 days) hemoglobin levels (n=62), therefore the power of this regression is very limited. This regression is summarized in Table 6. Demographic variables accounted for a small but significant amount of the variance when entered alone, $F(1,60)=4.6$, $p<.05$. The HBM did not contribute significantly to the equation, $F(5, 55)=1.2$, $p>.05$, however, SE did make a significant improvement in predictive ability, $F(4,51)=4.0$, $p<.01$.

A correlational matrix was created to test the first hypothesis, mainly, that self-care behaviors would not be correlated amongst themselves, but rather, some areas will be better adhered to than others. Significant correlations are illustrated in Table 7. Simple correlations found that fewer than predicted independent variables were correlated with criterion variables. Self efficacious beliefs in diet were found to be significantly related to dietary adherence ($r=.153$, $p<.05$). Similarly, self-efficacy for exercise was related to an increase in exercise adherence ($r=.284$, $p<.01$). Significance could not be found between areas of the HBM and adherence.

Insert Table 7 about here

Diagnostics

Despite "significant" findings (or a lack thereof), one cannot claim that a model does or does not predict the criterion variable until it can be shown that the model had, among others, sufficient power. Power (or alpha) is the probability that a significant relationship will be found if it actually exists. It can be improved upon in two ways; having a sufficient sample size to actually find significant results if they exist, and through the use of reliable measurements. A general "rule of thumb" (Green, 1991; Tabachnick & Fidell, 1994) in estimating sample size for regression analyses is that $N>50+8m$, where N=the number of participants and m=the number of predictors. Simple calculations for this study suggest a sample size equal to or greater than 146. In actuality, 156 patients agreed to participate in this investigation, however, only 118 questionnaires that were returned, met the inclusion criteria. Reliability is important to the power of an investigation, because without it, one cannot be certain that the constructs in question are actually and accurately being measured.

It has been highlighted in several places throughout this study that psychometrically sound measures were chosen for this study. However, due to advances in diabetes self-care, these measures become quickly outdated and had to be revised. Barring the ability to study test-retest reliability, Cronbach's alpha provides a sufficient test of reliability for cross-sectional data. Generally, alpha levels of .7 or higher are considered reliable. Therefore, to test if the revised measures were reliable insofar as they would not decrease the power of this study, Cronbach's apha was conducted for each

of the three questionnaires. For the five areas of Health Belief, perceived costs had the highest apha levels (.83) and was the only statistic above .7, although perceived severity could have been improved to α=.72 if one item had been discarded. The lowest levels were found for cues to action (α=.20), which is consistent with the literature which consistently finds this subscale to be the most unreliable. For self-efficacy, alpha levels were consistently high with the exception of dietary self-efficacy (α=.19). Adherence was the measure most affected by revisions, and this is apparent in alpha levels ranging from .29-.58. Even removing items from these subscales would not improve their reliability. Part of what influences alpha levels is the number and intercorrelations of the questions. For many of the adherence subscales, lack of adequate questions may have influenced reliability levels heavily. The combined effects of an insufficient sample size and poor reliability, especially for the dependant variable, begs the question of whether or not this study had sufficient power to find significance if it in fact existed. Hence, it is impossible to say that "no significance was found" because power was in all probability, too low to detect any effect sizes.

Assumptions

There are several statistical assumptions of multiple regression analysis that must be addressed. Failure to meet these assumptions can range from seriously affecting the analyses to minor hassles in interpretation. Scatter plots were first analyzed to see if the assumptions of linearity, normality and homogeneity were met (the assumptions of independence and model specification were not considered due to the nature of this investigation). By eyeballing the histogram for adherence to exercise, a normal curve was observed, without the presence of outliers. Further analysis confirmed low residual

and low leverage for this variable. Observation of the metabolic control variable also revealed normality. Although the maximum residual value was elevated (resid=3.3), leverage was not high. Adherence for medication taking, diet and glucose testing all revealed outliers on the histogram, and this was confirmed by elevated residuals, although leverage statistics were all found to be adequate. Similarly, tests of skewness and kurtosis all revealed values near 0 with the exception of adherence to glucose testing (kurtosis=5.39).

Multicollinearity was not found for this study, and tolerance levels were all found to be greater than .1. Heterogeneity of variance was observed most strongly for adherence to exercise and medication taking. Adherence to diet, glucose testing, and metabolic control were slightly more heteroscadastic, but not considerably so. Finally, linearity was not found for any of the predictor variables except metabolic control.

CHAPTER 3: DISCUSSION

This study attempted to strengthen a commonly used theoretical model of health behavior change by marrying it with an equally popular theory emphasizing self-evaluation. It was therefore hypothesized that the multidimensional nature of adherence could be better predicted by adding the construct of self-efficacy to the Health Belief Model of behavioral change. Unfortunately, this study did not find support for this hypothesis. There are many possible explanations for this lack of support; some found in the design and methodology of the study, and others more theoretical in nature. Each of these will be explored in some detail as well as discussing the present trend in health behavioral change and subsequently diabetes education.

Study Design

Although this study could not state conclusively that either the Health Belief Model or Self-Efficacy significantly predicted adherence in a diabetic regimen, this is not to say that this relationship does not exist. There were many limitations to this study which may have precluded such findings. Most noteworthy, the measures employed in this study, while used extensively in previous research, were not "up to date" insofar as their content validity was lacking due to extensive changes in diabetes self-care. For example, many original questions surrounding diet queried individuals after their fat or sugar intake, and some glucose testing questions asked about urine testing. These types of questions had to be revised and adapted to diabetes care in the 21st century (e.g. counting carbohydrates, using a pump for insulin administration, etc). In the end, all three measures had to be revised to varying degrees, with the Summary of Diabetes Self-Care Activities (adherence measure) being revised most extensively. For obvious reasons, the empirically established psychometric properties of these measures can no longer be cited or trusted for this study. Cronbach's alpha levels were found to be low for both the HBM and adherence measures. Thus, there is the inherent problem that the measures used were not in fact gauging the constructs they were intended to measure, or at a minimum, not as effectively as they might have with empirically supported instruments. Theoretically, computing composite rather than individual scores for each of the predictor and criterion variables may have increased power. This would reduce the number of predictor variables from 12 to 5, and a required sample size from 146 to 90 participants. Nevertheless, the literature has repeatedly shown that both self-efficacy and adherence are multifaceted (Glasgow, 1987; Bennett Johnson, 1992), and to do so would inherently (further) compromise the validity of the measures.

A question also arises regarding the conceptualization of some of the constructs investigated in this study. For example, it has long been established that exercise can both prevent/delay the onset of Type 2 diabetes, as well as being crucial in a diabetes regimen (type 1 and 2). What has not been established is how this exercise is best carried out. Recent trends have shifted away from an emphasis on intensive aerobic exercise, towards a wider range of moderate lifestyle activities which are easier to sustain (Ory, Jordan & Bazzarre, 2002). The format of the questions in this study did not operationally define exercise, thereby leaving individuals to discriminate the implied intensity level. Similarly, Nigg, Allegrante and Ory (2002) raise methodological questions in measuring health behavioral change. They deliberated on constructs such as adherence being better conceptualized as dichotomous or continuous variables. This study attempted to address this issue by separating adherence into areas of diet, exercise, medication taking and glucose testing, rather than a composite score of adherence. However, within these continuous categories may exist even more subcategories that were not investigated (e.g. adherence to counting carbohydrates at home but not in restaurants or at social events).

Theoretical Issues

There has already been some discussion regarding the operational definitions of several of the constructs of interest in this study. Operational definitions allow researchers to understand and measure the constructs under investigation more precisely, as well as providing an identical explanation to the participants of the study when appropriate. Prior to this, a more fundamental and theoretical quandary arises in deciding how to conceptualize a complicated and multifaceted construct such as adherence. An extensive review of the pitfalls of defining and measuring adherence has already been

discussed in the opening paragraphs of this paper. While rarely operationally defined, the implicit definition of adherence is "whether the patient performs the tasks definitive of medical treatment or a healthy lifestyle change" (pg. 449, Bellg, Resnick, Sharp Minicucci, Ogedegbe, Ernst, Borrelli, Hecht, Ory, Orwig, & Czajkowski, 2004). More recent attention has been given in the area of treatment fidelity and subsequently to teasing apart the various components of adherence as a construct (Bellg et. al., 2004; Nigg et. al., 2002). These investigators have separated what is commonly thought of as adherence or health behavioral change into 3 components: treatment enactment, treatment adherence, and treatment efficacy. Assuming that the health behavioral regimen has been presented in a coherent way that is clearly understood by the patient, *treatment enactment* refers to "the degree to which the state can be adopted in the appropriate life setting." (pg. 449, Bellg et. al., 2004). It is the extent to which the individual exercises the behavioral, cognitive or motivational state(s) dictated by the health care regimen, in the appropriate setting and at the appropriate time. As defined earlier, t*reatment adherence* refers to the widely held view of adherence (e.g. actually taking diabetes medication or exercising). Lastly, *treatment efficacy* refers to whether, having completed the prescribed behaviors, there is a measurable change in the health behavior under investigation (e.g. whether exercising actually improves hemoglobin A1c levels). Bellg and colleagues (2002) suggest that a study with poor enactment will most definitely result in poor adherence and efficacy; however, it is possible to have a study with good enactment but poor adherence or efficacy. The present study attempted to measure treatment adherence, but presupposed treatment enactment and efficacy (with the exception of HbA1c levels which have been found in the literature to correlate poorly

with self-care behaviors). It is possible that the lack of significant findings were a result of poor treatment enactment (e.g. failing to buy foods low in carbohydrates), which subsequently led to poor treatment adherence (e.g. not eating low carbohydrate meals). Without isolating these similar but distinct components of adherence, we cannot fully appreciate the lack of significant findings in the present study.

The intent of the present study was to increase the predictive ability of two primarily cognitive models of health behavioral change. Insofar as both theories emphasize the thoughts and beliefs motivating behavioral change, and self-efficacy specifically promotes the additional component of self-evaluation, a theoretically more comprehensive and powerful predictive model should emerge. Nevertheless, Nigg and colleagues (2002) have stated that traditional psychosocial factors are "necessary but not sufficient 'determinants' of health behavior" (pg. 671). Several researchers have suggested that there may be other factors, expressly emotional, that are neglected by Social Learning Theory and the Health Belief Model but which are important in "determining" health behavioral change (Bish, Sutton, & Golombok, 2000; Millar, 1997; Wdowik, Kendall, Harris & Auld, 2001). Indeed, at the very heart of cognitive-behavioral therapy, is the presupposition that cognitive, behavioral and affective variables interact with one another to determine the behavioral chain. Yet the majority of research in the area of health behavior change (including this study) fails to measure this area of individual differences. Particularly salient and worthy of investigation would be the impact of emotional factors on dietary and exercise regimens, since there is a reciprocal relationship between both of these variables with affect. It is possible that for health

behaviors (i.e. treatment enactment, adherence and efficacy) to be accurately understood and measured, a more comprehensive affective picture must emerge.

Insofar as this study intended to build upon previous research that has found less than expected predictability of the HBM and demonstrate the ability of self-efficacy to influence behavioral change, the very nature of the second proposed hypothesis (to better predict adherence with the construct of self-efficacy) dictated the statistical analyses of multiple regressions. However, many recent studies in the area of health behavior change view the role of self-efficacy as mediating this relationship. Ory and colleagues (2002) highlighted that self-efficacy and outcome expectations (another facet of Bandura's Social Learning Theory) were each found to be among the most common mediators in the relationship between exercise and nutrition with health behavior change. Although it was not feasible for the purposes of this study, future research (especially multi-site investigations where a high participant pool is available) may follow this example by conducting studies whereby path analyses can be conducted.

Armitage and Conner (2000) suggest that there are three different categories of social cognition models in the literature. The authors distinguish between motivational theories, behavioral enactment theories, and multi-stage models of behavioral change. Motivational theories, which include both the HBM and social cognitive model, among others, are believed by the authors to provide an incomplete explanation of health behaviors. Instead, they suggest that behavioral enactment models provide additional variables that mediate the relationship between intention and behavior. This is not unlike the conceptualization of self-efficacy highlighted by Ory et. al. (2002) in the preceding paragraph. Similarly, Armitage and Conner (2000) posit that multi-stage models also

elaborate on motivational theories by conceptualizing health behaviors in discrete stages. Indeed, Schwarzer's (1992, as cited in Armitage & Conner, 2000) health action process approach (HAPA) conceptualizes health behavioral change as a stage theory that includes a motivational phase and volitional phase. Schwarzer suggests that self-efficacy and outcome expectancies are both important in the motivational phase, whereby outcome expectancies precede self-efficacy (rather than being simultaneous predictors). Similarly, factors such as perceived susceptibility and perceived severity from the HBM are seen as more distal antecedents of outcome expectancies. Schwarzer would thereby explain the poor predictive utility of the current study according to this conceptualization of motivational variables. He also includes self-efficacy in the volitional phase of his approach, which is divided into planning, action and maintenance stages. Self-efficacy is said to play a pivotal role in the planning stage whereby individuals rely on optimistic self-beliefs when facing self-imposed challenges. These alternate conceptualizations of social cognitive models not only alter the role of self-efficacy and the HBM, but beg the question of whether motivational theories are too simplistic at their core. The impetus for the HBM was borne out of a desire to predict preventative health behaviors (usually requiring an isolated health-related behavior such as receiving an immunization). Thus, the HBM may fall short as a model for explaining daily health behaviors such as those required to maintain and treat a chronic illness like diabetes.

Lastly, the possibility exists that self evaluation is not a salient factor in health behaviors; either in directly predicting adherence, in mediating this relationship, or as a component of a multistage theory. Thus, even if a study could theoretically address all the limitations highlighted in this study, the possibility exists that self-efficacy would not

predict health behaviors. Alternative variables such as those discussed earlier (e.g. affect) or a plethora of others can be hypothesized to have this predictive ability. Nevertheless, without substantial empirical data, all of these possibilities are nothing more than educated guesswork.

Current Trends/ Future Research

A recent resurgence has occurred in the literature, whereby the theoretical models of behavioral change so popular in the 1980's are reappearing within the context of health promotion and education. The National Institute for Health Behavioral Change Consortium (BCC) is a multisite/ multibehavioral/ multitheoretical collection of 15 national studies being conducted with the common goal of creating innovative ways of intervening in health behaviors (Bellg et. al., 2004; Nigg et. al., 2002; Ory et. al., 2002). The "BCC approach" to understanding health promotion and behaviors is to expand theories focusing on individual health behavior change towards ecological or community models of intervention. Understanding individual psychology is then just one element in the social or environmental context of understanding motivation and change (Nigg et. al., 2002). Understanding the individual within the context of societal influences is not novel. Indeed, Bandura's Social Learning Theory (1977; 1986) emphasized the individual within his/her social environment. What is unique to research of the 21st century is the emphasis on public, not individual health promotion. While this approach cannot hope to be as concentrated as individual approaches, it is more cost effective and sustainable over time (Ory et. al., 2002). Hence, the BCC and other nationally funded research (e.g. National Research Council, 2001; Smedley & Syme, 2000) are attempting to go beyond epidemiological studies which link certain behaviors to health, towards

widespread policy changes and health promotion. The 15 multi-site approach endorsed by the BCC is one example of attempting to reach a wide range of individuals across the country. Similarly, the rationale for the multi-behavior approach attempts to target several harmful behaviors simultaneously. There is debate as to whether it is more effective to target behaviors individually or simultaneously and there are arguments for both sides. While there may be a greater impact and maintenance on the behavioral change when targeted as a whole, this may be overwhelming and overly complicated. The BCC philosophy defines "gateway behaviors" as those behaviors that when acted upon, have a positive influence on other co-occurring behaviors (Nigg et. al., 2002). In the end, many studies in the BCC allow the individual to choose what behaviors to target and in what order. Lastly, the BCC advocates a multi-theory approach to understanding health behavior change. In many of the national studies, both the HBM and self-efficacy have been endorsed as having treatment utility. Indeed, Nigg and colleagues (2002) suggest that testing theories against each other (rather than in isolation) allow comparisons if the same constructs are being measured but labeled differently, or whether different theories operationalize the same constructs differently. Comparing theories within the context of the same study can also aid in the predictive ability of any one theory in isolation (Nigg et. al., 2002). It would appear that the current study was following the current trend to improve prediction via a multi-theoretical approach. Nevertheless, as it was highlighted in the previous paragraphs, many of these studies view the role of self-efficacy in a slightly different manner than did the present study.

Adherence literature has long worked under the presupposition that lack of improvement in health care behaviors are the result of an unwillingness or inability of the

patient to adapt to the prescribed regimens. The relatively recent emphasis on treatment fidelity is changing this philosophy by focusing instead on methodological strategies to improve the reliability and validity of behavioral health care interventions. Metabolic control is an example of an outcome variable that has shown to have a very weak relationship with diabetes self-care behaviors. Belig and colleagues (2004) would explain this as an example of potentially adequate treatment enactment and adherence, but poor treatment efficacy. Understanding this subtle differentiation allows for an understanding of individual differences, which can then be applied to the increasingly popular community-based interventions. Allowing patients to choose the area(s) of intervention on which to focus, speaks to cognitions and beliefs in their ability to significantly impact "gateway behaviors". If nonadherence is one of the major obstacles to disease management, than preventative community-based programs not only save money in lost productivity and more intensive/expensive interventions, but they have the great potential to significantly minimize the threat of nonadherence.

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Appendix A

Informed Consent

Participant #

Drexel University
CONSENT TO PARTICIPATE
IN INVESTIGATIONAL RESEARCH

(1) **Participant's Name**: _____

(2) **Title of Research:** ***Living with diabetes: thoughts and feelings of individuals with Type 1 diabetes***

(3) **Purpose of Research**:

(a) To learn more about how live with a diagnosis of Type 1 diabetes

(4) **Procedures and Duration**: I understand the I will be asked to do the following:

(a) To provide information about myself, such as my age, race, and medical treatment. My name will not be on any materials retained in the study and this personal information will only be know to the research team.

(b) To fill out several brief questionnaires asking about my daily living with Type 1 diabetes, how I currently am feeling, and my thoughts about my diabetes diagnosis.

(5) **Risks and discomforts**: I have been told that the risks and/or discomforts of being in this study include:

(a) I may worry about who may have personal information about me. Since information about me is private, the researchers will not discuss my individual responses, but rather discuss everybody's responses collectively. Only the medical professionals involved in this study will see any responses.

(b) Completing the questionnaire may increase negative feelings because I am thinking about my daily regimen living with diabetes. If these thoughts or feelings make me feel worse, I can discuss them with any member of the research team.

(6) **Benefits**: I understand the following benefits may occur as a result of my participation in this study:

(a) My participation may help future patients with Type 1 diabetes by helping researchers to know more about the importance of what it is like to live with this disease. This information can lead to the development of important educational and counseling programs.

(b) I understand that I may not directly experience any benefits from participating in this study.

(7) **Refusal or Withdrawal from Participation**: I have been told that can refuse to join this study or change my mind about my continued participation at any time. Doing so will not affect my right to receive health care or any other services at Integrated Diabetes Services.

(8) **In case of Questions or Injury**: I understand the if I have any questions or believe that I have been injured in any way by participating in this research project, I should contact Dr. Arthur Nezu at telephone number 215-762-3679. If I have an adverse reaction or injury as a result of this study, I should also contract Drexel University Research Administration Office at 215-

(9) **Consent to Use Research Results and Confidentiality of Records**: As a participant in this research study, I have given my permission for Drexel University to keep, preserve, publish, use or dispose of the results of this investigation. In any publication, my identity will be kept confidential, but there is the possibility that records which identify me will be inspected by authorized individuals and agencies required by the law.

My medical records will be handled in an equally confidential manner.

(10)Participation Certification:

I have been informed of the reasons for this study. The study has been explained to me and I have had all my questions about the study answered. I have carefully read this consent form and received a copy.

Date: _____

Participant's name: _____

Participant's signature: _____

SIGNATURE OF WITNESS: _____

Appendix B

Demographic Form,

Self-Reported Measures

Participant #_____

Living with Diabetes

Patient Information

Your responses to the following questions will be kept confidential. This information will not be put in your medical record. No identification of individual participants will be made in any way.

1. Today's date: __/__/__ (date/mo/yr)
2. When were you first diagnosed as having diabetes?
   __/__ (mo/yr), at age___
3. Has your Health Care Professional recommended that you take insulin? If so, how often? (circle one)
   1. no (skip to question #5)
   2. once per day
   3. twice per day
   4. three times per day
   5. more than 3 times per day
   6. Pump Therapy
4. How long have you been taking insulin shots? (circle one)
   1. less than 6 months
   2. 6mo- 1year
   3. 1-5 years
   4. more than 5 years
5. How many times have you been told by a health care professional to test your blood-glucose levels?
   1. not been told to test (skip to question #6)
   2. 1-3 times per week
   3. daily
   4. twice daily
   5. 3-4 times per day
   6. 5+ times per day
6. Has your Health Care Professional recommended that you take oral medication(s) for your diabetes? If so, how often? (circle one):
   1. no (skip to question #8)
   2. once per day
   3. twice or more per day
7. How long have you been taking oral medication(s)? (circle one)
   1. less than 6 months
   2. 6mo- 1year
   3. 1-5 years
   4. more than 5 years

8. Has your Health Care Professional told you to take medications at certain times during the
day?
1. no
2. yes

9. Has your Health Care Professional told you to adjust your dosage of medication when exercising?
1. no
2. yes

10. Have you been told by a health care professional to limit the amount of calories you eat? (circle one):
1. no (skip to question #12)
2. yes

11. How long ago were you told to limit your amount of calories? (circle one)
1. less than 6 months
2. 6mo- 1year
3. 1-5 years
4. more than 5 years

12. Have you been told by a Health Care Professional to limit the amount of carbohydrates
you eat? (circle one):
1. no (skip to question #14)
2. yes

13. How long ago were you told to limit your amount of carbohydrates? (circle one)
1. less than 6 months
2. 6mo- 1year
3. 1-5 years
4. more than 5 years

14. Do you have a plan for matching your food consumption to the dosage of your insulin or medication(s)? (i.e. amount of food to dosage).
1.no
2.yes

15. Have you been given instructions of what to eat when you are hypoglycemic?
1. no
2. yes

16. Have you been given a specific exercise program that was recommended for your diabetes? (circle one)
1. no (skip to question #19)
2. yes

17. If yes, how many days per week?
1. 1
2. 2
3. 3
4. 4
5. 5
6. 6
7. 7

18. How long ago were you given this exercise program for your diabetes? (circle one)
    1. less than 6 months
    2. 6mo- 1year
    3. 1-5 years
    4. more than 5 years

19. How often has your Health Care Professional recommended that you engage in?
    1. eye exams (ophthalmologist)
       I----------I----------I----------I----------I----------I
       >1/yr 1/yr 2X/yr 4X/yr monthly daily
    2. seeing a podiatrist (foot doctor)
       I----------I----------I----------I----------I----------I
       >1/yr 1/yr 2X/yr 4X/yr monthly daily
    3. checking kidney functioning (microalbumin)
       I----------I----------I----------I----------I----------I
       >1/yr 1/yr 2X/yr 4X/yr monthly daily
    4. self foot inspection
       I----------I----------I----------I----------I----------I
       >1/yr 1/yr 2X/yr 4X/yr monthly daily
    5. dental checkup
       I----------I----------I----------I----------I----------I
       >1/yr 1/yr 2X/yr 4X/yr monthly daily
    6. I was never told any of these

20. Which if any, of the following problems sometimes associated with diabetes have you experienced? (circle all that apply):
    1. mild low blood sugar if so, how often? _____/month
    2. severe low blood sugar (requiring assistance) if so, _____/12 mo
    3. ketoacidosis if so, _____/12 mo
    4. heart problems
    5. sexual difficulties
    6. damage to the retina of the eye
    7. nerve damage (e.g. numbness or tingling of the hands or feet, or foot ulcers)
    8. kidney problems
    9. none of the above

21. What other major health problems do you have (please specify): _____
_____
_____
_____
_____

22. What is your date of Birth?: __/__/__ (date/mo/yr)

23. What is your gender?
    1.M
    2.F

24. What is your approximate height and weight?
    1. Height ____ft ___inches
    2. Weight _____lbs

25. What is your race?: (circle one):
    1. Caucasian
    2. African American
    3. Hispanic
    4. Asian
    5. Native American
    6. other (please specify) _____

26. What is your current marital status? (circle one):
    1. married
    2. widowed
    3. divorced
    4. separated
    5. never married
27. What is your current employment status? (circle one)
    1. employed full time
    2. employed part time
    3. unemployed (but physically able to work)
    4. unable to work due to health
    5. retired
28. What is your annual income from all sources (circle one):
    1. >$20,000
    2. $20,000-40,000
    3. $41,000-60,000
    4. 61,000-100,000
    5. $100,000+
29. How many years of education have you completed? (circle one):
    1. 8 or less
    2. between 9 and 12 (some high school)
    3. 12 (high school graduate)
    4. some college or associates degree
    5. bachelors degree
    6. post bachelors degree
30. Who is your primary medical provider for the treatment of your diabetes? (circle one)
    1. I am not been seen by anyone for my diabetes (skip to question #32)
    2. Endocrinologist
    3. Primary Physician/ General Practitioner
31. When was your last medical appointment with this doctor? (circle one)
    1. within the last month
    2. within the last 3months
    3. within the last 6 months
    4. within the last year
    5. more than 1 year ago
32. Have you ever sought services of a Diabetes Educator in the past?
    3. no
    4. yes
33. How many times in the last year have you seen a Diabetes Educator?

1. 0
2. 1-2
3. 3-6
4. 6+

34. Have you ever received psychological services in the past?
    1. no (skip to question #36)
    2. yes

35. Were the services you received related to your diagnosis of diabetes? (circle all that apply):
    1. Yes, diabetes related
    2. Related to diabetes and other reasons (specify:_____)
    3. Not related to diabetes, just other reasons (specify: _____)

36. Are you currently receiving psychological services:
    1.Yes
    2.No

37. Have you ever experienced any emotional/mental health difficulties?
    1. Yes
    2. No

If yes, please specify:

_____

Participant #_____

Living with Diabetes

Activities Questionnaire

After considering the difficulty of each activity listed below, rate how certain you are that you realistically could perform each activity (if you decided to) over the next several months. Select any number between –100 and +100 that best represents how you feel using the scale below.

-100 **0** **+100**

Completely certain that I could not	*Moderately certain that I could not*	*Uncertain as to whether or not I could*	*Moderately certain that I could*	*Completely certain that I could*

GLUCOSE TESTING **CERTAINTY RATING (-100 to +100)**

1. I could test my (blood) glucose level at least once a week over the next several months. _____

2. I could test my glucose level at least every other day. _____

3. I could test my glucose level at least once a day. _____

4. I could test my glucose level at least twice a day. _____

5. I could test my glucose level as instructed by my Health Care Professional over the _____

next several months.

6. I could test my glucose levels regularly when I am at home. _____

7. I could test my glucose levels regularly at work/school. _____

8. I could test my glucose levels regularly while I am on trips away from home. _____

-100 **0** **+100**

Completely certain that I could not | *Moderately certain that I could not* | *Uncertain as to whether or not I could* | *Moderately certain that I could* | *Completely certain that I could*

EXERCISE

CERTAINTY RATING **(-100 to +100)**

9. I could exercise for at least 20 minutes once per week over the next several months. _____

10. I could exercise for at least 20 minutes 2 times each week. _____

11. I could exercise for at least 20 minutes three times each week. _____

12. I could exercise for at least 20 minutes four times each week. _____

13. I could exercise for at least 20 minutes five times each week. _____

14. I could exercise for at least 20 minutes six times each week. _____

15. I could exercise for at least 20 minutes every day each week. _____

EATING HABITS

16. I could limit my caloric intake as

instructed by my physician or nutritionist over the next several months. _____

-100 **0** **+100**

Completely certain that I could not | *Moderately certain that I could not* | *Uncertain as to whether or not I could* | *Moderately certain that I could* | *Completely certain that I could*

EATING HABITS (CONTINUED) **CERTAINTY RATING (-100 to +100)**

17. I could limit my caloric intake when traveling. _____

18 I could limit my caloric intake when at parties and social occasions. _____

19. I could limit my caloric intake when eating at restaurants. _____

20. I could match my food to medication/ insulin when traveling. _____

21. I could match my food to medication/ insulin when at parties and social occasions. _____

22. I could match my food to medication/ insulin when eating at restaurants. _____

23. I could limit my carbohydrate intake when traveling. _____

24. I could limit my carbohydrate intake when at parties and social occasions. _____

25. I could limit my carbohydrate intake when eating at restaurants. _____

-100 **0** **+100**

Completely certain that I could not | *Moderately certain that I could not* | *Uncertain as to whether or not I could* | *Moderately certain that I could* | *Completely certain that I could*

MEDICATION TAKING (Please indicate "-8" if you are not prescribed diabetes medication).

CERTAINTY RATING (-100 to +100)

26. I could regularly take my diabetes medication (insulin or pills) as prescribed by my Health Care Professional over the next several months. _____

27. I could take my diabetes medication at the times I am supposed to over the next several months. _____

28. I could take my diabetes medication regularly even when away from home. _____

29. I could adjust my level of diabetes medication to changes in my activity (exercise) level. _____

Participant #_____

Living with Diabetes

Diabetes Self-Care Questionnaire

NUTRITIONAL REGIMEN

The first few questions ask about your eating habits over the last 7 days. If your Health Care Professional has not given you a specific diet, answer Question 1 according *to the general guidelines you have received.*

1. What percentage of the time did you successfully limit your carbohydrates as recommended
for healthy eating for diabetes control?

Not Recom-mended	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

2. What percentage of the time did you successfully limit your calories as recommended in healthy eating for diabetes control?

Not Recom-mended	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

EXERCISE

3. In the last 7 days, how many days have you participated in at least 20 minutes of physical exercise (other than what you do around the house or as part of work)?

0	1	2	3	4	5	6	7

GLUCOSE TESTING

4. How many times in the last week (that you were not sick) did you test your glucose (blood sugar) levels?

a/ 0 b/ 1-2 c/ 3-4 d/ 5-6 e/ 7-8 f/ 9-13 g/ 14-20 h/ 21-27 i/ 28+

DIABETES MEDICATION

5. How many insulin injections/ boluses did you take in the last day?

1. 0
2. 1
3. 2
4. 3
5. 4+
6. I do not take insulin
7. I am on Pump therapy

6. In the last 7 days, how many times did you forget to take your insulin?

0	1	2	3	4	5	6	7	8	9	10

7. In the last 7 days, how many times did you forget to take your medication?

0	1	2	3	4	5	6	7	8	9	10

8. In the last 7 days, how many times did you mistakenly taken the wrong amount of medication?

0	1	2	3	4	5	6	7	8	9	10

9. What percentage of time did you match your insulin/ medications to the foods you have or were about to consume?

Not Recom-mended	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100

DIABETES COMLPLICATIONS

10. When was your last visit to an ophthalmologist to include testing for retinopathy related to diabetes?

a) within the last 6 months
b) within the last year
c) within the last 18 months
d) within the last 24 months
e) approximately 2-5 years ago
f) more than 5 years ago

11. When was your last visit to a podiatrist to include testing for complications related to diabetes?

a) within the last month
b) within the last 3 months
c) within the last 6 months
d) within the last 12 months
e) within the last 18 months
f) within the last 24 months
g) approximately 2-5 years ago
h) more than 5 years ago
i) never

12.When was your last kidney function test?

a) within the last 3 months
b) within the last 6 months
c) within the last 12 months
d) within the last 18 months
e) within the last 24 months

f) approximately 2-5 years ago
g) more than 5 years ago
h) never

13. When was your visit to the dentist?

a) within the last 3 months
b) within the last 6 months
c) within the last 12 months
d) within the last 18 months
e) within the last 24 months
f) approximately 2-5 years ago
g) more than 5 years ago
h) never

14. In the last 7 days, how often have you inspected your feet?

0	1	2	3	4	5	6	7

15. In the last 30 days when your blood sugar has been low, what percentage of the time did you eat appropriate amounts of food (i.e. do not over/under eat)?

I never get low blood sugar	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100

16. When your blood sugar is high, what percentage of the time do you correct using appropriate amounts of insulin?

I do not use insulin for this reason	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100

Participant #_____

Living with Diabetes

Health Belief Questionnaire

People can have very different feelings about having the same illness. We are interested in how you personally feel about having diabetes.

In the first section of this questionnaire we want to find out how serious having diabetes or some of its complications seems to you. Please note that we are interested in your personal feelings and about the severity of the illness and not what your doctor or family or friends may think.

Please circle the statement that comes closest to expressing your feelings. Circle only one. Even though you don't feel the description fits you exactly. Please circle the number that comes closest and write you own description on the line marked "comment".

Part I

1. I think diabetes:
   A. Is not a serious illness at all (I don't understand all the fuss that's made).
   B. Is not a very serious illness (if you get sick the doctors can always fix you up and there is no harm done).
   C. Can be a serious illness (if you follow the rules you will be okay but if you don't the consequences can be bad).

D. Is a fairly serious illness (if you don't follow the rules, the consequences down the road will probably be terrible).
E. Is an extremely serious illness (it's like having an illness like cancer in many ways).

Comments:
_____

2. To me, blindness would:
   A. Not be as bad as people think
   B. Be bad but I'd learn to read Braille, and I'd be okay
   C. Neutral
   D. Be very bad; it would take me a long time to adjust to.
   E. Be so terrible I don't know if I could stand to live with it.

Comments:
_____

3. To me, loosing a leg would:
   A. Not be as bad as people think.
   B. Be bad but I'd learn to walk with an artificial leg and I'd be okay.
   C. Neutral
   D. Be very bad; it would take me a long time to adjust to.
   E. Be so terrible I don't know if I could bear to live with it.

Comments:
_____

4. In general, the complications associated with diabetes seem to me to:
   A. Not be as bad as people think.
   B. Be bad but I'd get through okay.
   C. Neutral
   D. Be very bad; it would be a struggle to adjust.
   E. Be so terrible I don't think I could stand to live with them.

Comments:
_____

Part II.

1. i/ I think there is about a X% chance that I will someday go blind because of my diabetes.
   A. 0-19% chance
   B. 20-39% chance
   C. 40-59% chance
   D. 60-79% chance
   E. 80-100% chance

Comments:

_____

ii/ How much of your estimate is based on how well you adhere with your regimen (that is, stick to your diet, test for sugar, etc.)

A. None of my estimate
B. Some of my estimate
C. A moderate amount of my estimate
D. A lot of my estimate
E. Almost all of my estimate.

Comments:

_____

iii/ How much of your estimate is based on the disease (regardless of your adherence)?

A. None of my estimate
B. Some of my estimate
C. A moderate amount of my estimate
D. A lot of my estimate
E. Almost all of my estimate.

Comments:

_____

2. i/ I believe there is about a X% chance that I will someday loose a foot or leg from diabetic complications.

A. 0-19% chance
B. 20-39% chance
C. 40-59% chance
D. 60-79% chance
E. 80-100% chance

Comments:

_____

ii/ How much of your estimate is based on how well you adhere with your regimen (that is, stick to your diet, test for sugar, etc.)

A. None of my estimate
B. Some of my estimate
C. A moderate amount of my estimate
D. A lot of my estimate
E. Almost all of my estimate.

Comments:

_____

iii/ How much of your estimate is based on the disease (regardless of your adherence)?

A. None of my estimate
B. Some of my estimate

C. A moderate amount of my estimate
D. A lot of my estimate
E. Almost all of my estimate.

Comments:
_____

3. i/ I believe there is about a X% chance that I will someday have to be on a kidney machine (renal dialysis) because of kidney failure.
A. 0-19% chance
B. 20-39% chance
C. 40-59% chance
D. 60-79% chance
E. 80-100% chance

Comments:
_____

ii/ How much of your estimate is based on how well you adhere with your regimen (that is, stick to your diet, test for sugar, etc.)
A. None of my estimate
B. Some of my estimate
C. A moderate amount of my estimate
D. A lot of my estimate
E. Almost all of my estimate.

Comments:
_____

iii/ How much of your estimate is based on the disease (regardless of your adherence)?
A. None of my estimate
B. Some of my estimate
C. A moderate amount of my estimate
D. A lot of my estimate
E. Almost all of my estimate.

Comments:
_____

4. i/ I think that there is about a X% chance that I will suffer from some sort of serious complications of diabetes:
A. 0-19% chance
B. 20-39% chance
C. 40-59% chance
D. 60-79% chance
E. 80-100% chance

Comments:

_____

ii/ How much of your estimate is based on how well you adhere with your regimen (that is, stick to your diet, test for sugar, etc.)

A. None of my estimate
B. Some of my estimate
C. A moderate amount of my estimate
D. A lot of my estimate
E. Almost all of my estimate.

Comments:

_____

iii/ How much of your estimate is based on the disease (regardless of your adherence)?

A. None of my estimate
B. Some of my estimate
C. A moderate amount of my estimate
D. A lot of my estimate
E. Almost all of my estimate.

Comments:

_____

Part III

1. Having to limit the amount of everything I eat and counting carbohydrates in everything I eat is:

A. A minor inconvenience (I don't care for carbs anyway).
B. Moderately inconvenient
C. A major inconvenience (but it's not the worst thing in the world).
D. Difficult for me (I love carbs)
E. Terrible for me (I can hardly stand it!)
F. Not applicable to me

Comments:

_____

2. Having to take insulin is:

A. A minor inconvenience (It really doesn't bother me much).
B. Moderately inconvenient
C. A major inconvenience (but it's not the worst thing in the world).
D. Difficult for me (I dislike injections very much)
E. Terrible for me (I can hardly stand getting or giving myself injections)
F. Not applicable to me

Comments:

_____

3. Having to test my blood sugar is:
   A. A minor inconvenience
   B. Moderately inconvenient
   C. Very inconvenient
   D. Extremely difficult for me (Pricking my finger is fairly painful)
   E. Terrible for me (I can hardly stand getting to prick my finger

Comments:

_____

4. Keeping regular hours and eating on schedule is:
   A. A minor inconvenience (with respect to my social and personal activities).
   B. Moderately inconvenient (it occasionally disrupts my social and personal activities)
   C. A major inconvenience (it often disrupts my social and personal activities).
   D. Difficult for me (it usually causes major disruptions in my social and personal activities)
   E. Terrible for me (it constantly ruins my social and personal activities)

Comments:

_____

5. Seeing a physician as often as I am required because of my diabetes is:
   A. A minor inconvenience
   B. Moderately inconvenient
   C. A major inconvenience
   D. Difficult for me (it interferes greatly with my schedule at school, work, or home)
   E. Terrible for me (it's almost impossible given my life situation)

Comments:

_____

6. The financial costs of my diabetes:
   A. Have very little impact on me or my family economically.
   B. Are moderate (i.e. I/my family can handle it without too much problem)
   C. Are high (but I/my family can still handle it)
   D. Are a great financial burden for me and/or my family (i.e. it is difficult to handle)
   E. Are terrible and have caused great hardships for me and/or my family (i.e. it is almost impossible to handle)

Comments:

_____

Answer #7 only if you drink alcohol

7. The limit my diabetes puts on drinking alcohol is:

A. Not a problem for me
B. A minor problem for me
C. Somewhat of a problem for me
D. A major problem for me
E. A terrible problem for me

Comments:
_____

Part IV

1. I believe that keeping my blood sugar as close to normal as possible:
   A. Will have no effect whatever on preventing complications later in life
   B. Probably won't have much of an effect on preventing complications later in life
   C. May decrease the chance of having serious complications later in life
   D. Will probably decrease the chance of having serious complications later in life
   E. Will greatly decrease the chances of my having serious complications later in life

Comments:
_____

2. When my blood sugar is "normal":
   A. I actually feel worse- like I'm having an insulin reaction
   B. I'm worried about getting an insulin reaction
   C. I don't feel any different than when it's high
   D. I feel better (more clearheaded, less tired, etc) than when it's high
   E. I feel great

Comments:
_____

3. When I stick to my diet and eat on a regular schedule:
   A. I don't feel any better physically than when I don't stick to my regimen
   B. I might feel a little better physically
   C. I feel somewhat better physically
   D. I feel good physically
   E. I feel great physically

Comments:
_____

4. I believe that testing my blood-sugar by examining my blood is:
   A. Is completely useless in regulating my diet and insulin dosage
   B. Has a purpose but too much of a hassle
   C. Is somewhat helpful in regulating my diet and insulin dosage
   D. Is really quite helpful in regulating my diet and insulin dosage

E. Is extremely helpful in regulating my diet and insulin dosage

Comments:

_____

5. When I test my blood sugar regularly like I'm supposed to:
   A. It doesn't make any difference in how I feel about myself
   B. I feel okay about myself
   C. I feel good about myself for doing the right thing
   D. I feel very good about myself
   E. I feel really good about myself for doing the right thing

Comments:

_____

6. Testing my blood sugar:
   A. Has no effect on how I feel physically on a day-to-day /week-to-week basis
   B. Might be slightly helpful in enabling me to feel better physically on a day-to-day/week-to-week basis
   C. Is definitely somewhat helpful in enabling me to feel better on a day-to-day/week-to-week basis
   D. Is very helpful in enabling me to feel better physically on a day –to-day/week-to-week basis
   E. Is extremely helpful in enabling me to feel better physically on a day-to-day/week-to-week basis

Comments:

_____

Part V

1. Which of the following statements best describes your experiences with being able to tell when your blood sugar is high?
   A. I can never tell (i.e. the results of my testing are always a complete surprise to me)
   B. I can rarely tell (i.e. if I did not test I probably would not realize my sugar was high)
   C. I can sometimes tell (i.e. when my sugar is high, it sometimes makes me feel different)
   D. I can usually tell (i.e. when my sugar is high, it usually feels different)
   E. I can always tell (i.e. when my sugar is high, it always feels different)

Comments:

_____

2. Which of the following statements best describe your experience with being able to tell when you're getting low blood-sugar (hypoglycemia)?
   A. I never seem to be able to prevent insulin reactions (i.e. they always seem to just happen all of a sudden)

B. I have been able to prevent insulin reactions in the past but I don't know how I did it
C. I can sometimes tell when my sugar is getting low early enough to prevent a reaction but other times they seem to creep up on me all of a sudden
D. I can often tell if my sugar is low early enough to prevent a reaction
E. I can always tell if my sugar is low early enough to prevent a reaction

Comments:

_____

3. How often do people in your family or your friends remind you about things you're supposed to do because of your diabetes?

A. Almost never
B. Once every month or so
C. Once every week or so
D. Once a day
E. Several times a day

Comments:

_____

4. In terms of remembering to test my sugar, eat, take medications/insulin etc., I:

A. *Ignore* time in terms of eating, insulin/medication etc.
B. Am aware of the time but don't necessarily eat/take insulin/medication when I should
C. *Kind of* keep track of the time to eat and take insulin/medication within an hour or so of the appropriate time
D. Make a really good effort to monitor the time but don't always follow through with taking my insulin within a few minutes of when I should
E. *Carefully* monitor what time it is so I can eat and take my insulin within a few minutes of when I should

Comments:

_____

Table 1. Demographic Characteristics of *Living with Diabetes* Participants

Variable	Frequency	%
Gender		
Male	46	38.7
Female	72	60.5
Age (yrs)		
18-28	21	15.8
29-39	28	23.5
40-50	27	22.7
51-61	26	22
62-73	16	13.3
Type of DM		
Type 1	82	68.9

Type 2	11	9.2
Ethnicity		
Caucasian	106	89.1
Non Caucasian	12	10.1
Marital Status		
Married	59	49.6
Widowed	6	5.0
Divorced	9	7.6
Separated	4	3.4
Never Married	40	33.6
Education (yrs)		
Between 9 and 12 (some HS)	4	3.4
12 (HS graduate)	14	11.8
Some college	34	28.6
Bachelors	29	24.4
Post Bachelors	37	31.1
Income (annual)		
<$20,000	25	21.0
$20-40,000	26	21.8
$41-60,000	23	19.3
$61-100,000	21	17.6
$100,000+	18	15.1

Table 1 (con't)

Variable	**Frequency**	**%**
Years since DM dx		
1-15	48	40.3
16-31	42	35.4
32-47	25	20.1
48-60	3	2.4
Diabetes Complications		
Mild low blood sugar	91	58.0
Severe low blood sugar	52	33.1
Ketoacidosis	25	15.9
Heart Problems	18	11.5
Sexual Difficulties	15	9.6
Damage to retina	22	14.0
Nerve Damage	24	15.3

Kidney Problems	10	6.4
Primary medical provider (DM)		
Not being seen by anyone	2	1.7
Endocrinologist	92	77.3
Primary Physician/GP	24	20.2

Table 2. Multiple Regression Analysis for Dietary Adherence

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.130(a)	.017	-.009	1.00865518	.017	.653	3	114	.583	
2	.263(b)	.069	.001	1.00364722	.052	1.228	5	109	.301	
3	.334(c)	.111	.010	.99924286	.042	1.241	4	105	.298	1.878

a Predictors: (Constant), YearsDM, gender, current age of participant
b Predictors: (Constant), YearsDM, gender, current age of participant, Zscore(HBMpercosts), Zscore(HBMpersev), Zscore(HBMpersus), Zscore(HBMCTA), Zscore(HBMperben)
c Predictors: (Constant), YearsDM, gender, current age of participant, Zscore(HBMpercosts), Zscore(HBMpersev), Zscore(HBMpersus), Zscore(HBMCTA), Zscore(HBMperben), Zscore(SEgluc), Zscore(SEdiet), Zscore(SEmeds), Zscore(SEexer)
d Dependent Variable: Zscore(Adherdiet)

Table 3. Multiple Regression Analysis for Exercise Adherence

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.198(a)	.039	.014	.99712569	.039	1.555	3	114	.204	
2	.302(b)	.091	.024	.99198134	.052	1.237	5	109	.297	
3	.409(c)	.167	.072	.96727040	.076	2.410	4	105	.054	2.163

a Predictors: (Constant), YearsDM, gender, current age of participant
b Predictors: (Constant), YearsDM, gender, current age of participant, Zscore(HBMpercosts), Zscore(HBMpersev), Zscore(HBMpersus), Zscore(HBMCTA), Zscore(HBMperben)
c Predictors: (Constant), YearsDM, gender, current age of participant, Zscore(HBMpercosts), Zscore(HBMpersev), Zscore(HBMpersus), Zscore(HBMCTA), Zscore(HBMperben), Zscore(SEgluc), Zscore(SEdiet), Zscore(SEmeds), Zscore(SEexer)
d Dependent Variable: Zscore(Adherexercise)

Table 4. Multiple Regression Analysis for Glucose Testing Adherence

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.262(a)	.069	.044	.98071737	.069	2.811	3	114	.043	
2	.331(b)	.109	.044	.98088328	.041	.992	5	109	.426	
3	.358(c)	.128	.029	.98867488	.019	.572	4	105	.683	1.917

a Predictors: (Constant), YearsDM, gender, current age of participant
b Predictors: (Constant), YearsDM, gender, current age of participant, Zscore(HBMpercosts), Zscore(HBMpersev), Zscore(HBMpersus), Zscore(HBMCTA), Zscore(HBMperben)
c Predictors: (Constant), YearsDM, gender, current age of participant, Zscore(HBMpercosts), Zscore(HBMpersev), Zscore(HBMpersus), Zscore(HBMCTA), Zscore(HBMperben), Zscore(SEgluc), Zscore(SEdiet), Zscore(SEmeds), Zscore(SEexer)
d Dependent Variable: Zscore(Adhergluctest)

Table 5. Multiple Regression Analysis for Medication Taking Adherence

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.156(a)	.024	-.001	1.00298431	.024	.944	3	114	.422	
2	.258(b)	.067	-.002	1.00322017	.042	.989	5	109	.428	
3	.287(c)	.083	-.022	1.01331468	.016	.460	4	105	.765	2.274

a Predictors: (Constant), YearsDM, gender, current age of participant
b Predictors: (Constant), YearsDM, gender, current age of participant, Zscore(HBMpercosts), Zscore(HBMpersev), Zscore(HBMpersus), Zscore(HBMCTA), Zscore(HBMperben)
c Predictors: (Constant), YearsDM, gender, current age of participant, Zscore(HBMpercosts), Zscore(HBMpersev), Zscore(HBMpersus), Zscore(HBMCTA), Zscore(HBMperben), Zscore(SEgluc), Zscore(SEdiet), Zscore(SEmeds), Zscore(SEexer)
d Dependent Variable: Zscore(adhermeds)

Table 6. Multiple Regression Analysis for Metabolic Control (HbA1c)

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.267(a)	.071	.056	.97159870	.071	4.618	1	60	.036	
2	.402(b)	.162	.070	.96421207	.090	1.185	5	55	.329	
3	.601(c)	.361	.236	.87396879	.200	3.986	4	51	.007	2.019

a Predictors: (Constant), current age of participant
b Predictors: (Constant), current age of participant, Zscore(HBMpercosts), Zscore(HBMpersev), Zscore(HBMpersus), Zscore(HBMperben), Zscore(HBMCTA)
c Predictors: (Constant), current age of participant, Zscore(HBMpercosts), Zscore(HBMpersev), Zscore(HBMpersus), Zscore(HBMperben), Zscore(HBMCTA), Zscore(SEgluc), Zscore(SEexer), Zscore(SEmeds), Zscore(SEdiet)
d Dependent Variable: Zscore: HbA1c

Table 7. Correlational Matrix for criterion and predictor variables

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Demographic Variables																
1.Age			.49**													
2.Gender															.17*	
3.Yrs DM															.17*	
HBM																
4.Perceived benefits		.18*	-.22**													
5.Perceived suscept						.18*										
6.Perceived severity															.16*	
7.Perceived costs				-.31**				.24**				.16*				
8.Cues to action	-.23**												.16*			
SE																
9.Medication taking	.20*	-.23**						.20*		.17*						
10.Exercise			-.19*	-.30**			.19*							.28**		
11.Diet	.20*		.20*							.17*				.18*	.15*	
12.Glucose testing										.16*						
Adherence																
13. Medication taking														-.19*		
14.Exercise																
15.Diet														.23**		
16.Glucose testing																

*p<.05
**p<.01

Vita

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Hahnemann University Hospital, ER~ Kessler Rehabilitation Hospital ~ Health Psychology/The Center for Behavioral Medicine and Mind/Body Studies ~ Controlled Environment Oncology Unit (CEOU) and General Inpatient Oncology Unit ~ Project S.T.O.P. (Sex Offender Treatment for Persons with Mental Retardation) ~ Project Challenge ~ The Genesis Cancer Coping Project ~ Weight Management Program ~ Mental Health Program Specialist

PUBLICATIONS:

Nezu, A.M., Maguth Nezu, C., Peacock, M.A. & **Girdwood, C.P**. (in press). Case formulation in cognitive-behavior therapy. In S.N. Haynes & E. Heiby (Eds.)., Behavioral Assessment, Vol 3 of the Comprehensive Handbook of Psychological Assessment. New York: Wiley.

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McClure, K., Nezu, A.M., Nezu, C.M., **Girdwood, C.P**., & Russell, M. (2000). Couples coping with cancer. Poster presented at the Association for Advancement of Behavior Therapy, New Orleans, LA.

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